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Lay Summary

The Medicines Healthcare products Regulatory Agency (MHRA) granted Galpharm Healthcare Limited Marketing Authorisations (licences) for the medicinal products Galpharm Extra Power Pain Reliever Caplets (PL 16028/0147-8) on 23rd September 2009. These are general sales list (GSL) medicines and are available to the general public without prescription.


Alternative names for PL 16028/0148 are Galpharm Extra Power Pain Reliever Caplets, Lloyds Pharmacy Extra Power Pain Reliever Caplets and Tesco Extra Pain Reliever Caplets. However; for ease of reading the report PL 16028/0147 will be referred to only as Galpharm Extra Power Pain Reliever Caplets.

These applications are identical to a previously granted application for Extra power Pain Reliever Tablets (PL 12063/0009), granted to Wrafton Laboratories Limited on 11th January 1994 and, as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Galpharm Extra Power Pain Reliever Caplets outweigh the risks; hence Marketing Authorisations have been granted.
SCIENTIFIC DISCUSSION

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Overall conclusions and risk benefit assessment Page 10
INTRODUCTION

The MHRA granted marketing authorisations for the medicinal product Galpharm Extra Power Pain Reliever Caplets (PL 16028/0147-8) to Galpharm Healthcare Limited on 23rd September 2009. The product is a general sale list medicine.

These applications were submitted as simple abridged applications according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Extra power Pain Reliever Tablets (PL 12063/0009), granted to Wrafton Laboratories Limited on 11th January 1994.

Galpharm Extra Power Pain Reliever Caplets contains the active ingredients, aspirin, paracetamol and caffeine. Aspirin belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body’s response to pain, swelling and high temperature. Paracetamol centrally acting analgesic (a pain killer that acts on pain centres in the brain), which is used to relieve mild to moderate pain as well as to reduce increased body temperature (anti-pyretic) and caffeine is a mild stimulant.

These tablets are for the relief of mild to moderate pain including headache, migraine, toothache, nerve pain, sore throat and period pains. They are also for symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, flu, feverishness and feverish colds.

No new data were submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) has been generated for it.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 16028/0147-8

PROPRIETARY NAME: PL 16028/0147
- Boots Aspirin Extra Tablets
- Asda Extra Power Pain Reliever Tablets
- Galpharm Extra Power Pain Reliever Caplets
- Lloyds Pharmacy Extra Power Pain Reliever Caplets
- Morrisons Extra Power Pain Reliever Caplets
- Numark Extra Power Pain Reliever Tablets
- Paramed Extra Power Pain Reliever Tablets
- Sainsbury’s Extra Power Pain Reliever Caplets
- Superdrug Extra Power Pain Reliever
- Tesco Extra Power Pain Reliever Caplets
- Wilko Extra Power Pain Reliever Tablets

PL 16028/0148
- Galpharm Extra Power Pain Reliever Caplets
- Lloyds Pharmacy Extra Power Pain Reliever Caplets
- Sainsbury’s Extra Power Pain Reliever Caplets
- Tesco Extra Power Pain Reliever Caplets

ACTIVE(S): Aspirin, Paracetamol, Caffeine

COMPANY NAME: Galpharm Healthcare Limited

E.C. ARTICLE: Article 10c of Directive 2001/83/EC

LEGAL STATUS: GSL

1. INTRODUCTION
These are simple, informed consent applications for Galpharm Extra Power Pain Reliever Tablets (PL 16028/0147) and Galpharm Extra Power Pain reliever Caplets (PL 16028/0148) submitted under Article 10c of Directive 2001/83/EC. The proposed MA holder is Galpharm Healthcare Limited, Upper Cliffe Road, Dodworth Business Park, Dodworth, South Yorkshire, S75 3SP, UK.

These applications cross-refer to the Marketing Authorisation for Extra Power Pain Reliever Tablets granted to Wrafton Laboratories Limited (PL 12063/0009), approved on 11th January 1994. The current applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name(s)
The proposed names of the products; Galpharm Extra Power Pain Reliever Caplets and all the alternative names listed above for PL 16028/0147 and PL 16028/0148 are satisfactory. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The product contains the active ingredients aspirin, paracetamol and caffeine, equivalent to 300mg, 200mg and 45mg respectively. The tablets/caplets are packaged in either blister packs or drums. The blister packs are composed of either opaque unplastersised polyvinyl chloride (UPVC)/Aluminium foil(Al) or white PVC/Al, or opaque UPVC/paper. The
drums are composed of polypropylene with high density polyethylene (HDPE) child resistant caps. The blister packs are packed into boxboard cartons in blister counts of 24 and 32 tablets. Each polypropylene drums hold 25 tablets.

The proposed shelf-life is 3 years with no specific storage conditions; this is consistent with the details registered for the cross-reference product.

### 2.3 Legal status
On approval, the product will be available as a general sale list (GSL) medicine which will be available to the general public without a prescription.

### 2.4 Marketing authorisation holder/Contact Persons/Company
Galpharm Healthcare Limited, Upper Cliffe Road, Dodworth Business Park, Dodworth, South Yorkshire, S75 3SP, UK.

The QP responsible for pharmacovigilance is stated and his CV is included.

### 2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

### 2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

### 2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

### 2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product.

### 2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

### 2.10 TSE Compliance
A declaration is given that no materials of animal and/or human origin are contained or used in the manufacturing process for the medicinal product. This is consistent with the approved cross-reference product.

### 3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.
4. **PRODUCT NAME & APPEARANCE**
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. **SUMMARY OF PRODUCT CHARACTERISTICS**
The proposed summary is consistent with the details registered for the cross-reference product.

6. **PATIENT INFORMATION LEAFLET/CARTON**
   **PIL**
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

   The PIL is in compliance with current guidelines and user testing results have been submitted. The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

   **Carton and blister**
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. **CONCLUSIONS**
The data submitted with these applications are acceptable. Marketing Authorisations should be granted.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.
CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY
Paracetamol is a well known drug and has been used as an analgesic for many years. Aspirin has been used for many years in the management of pain, swelling and fever. These applications are identical to the previously granted application for Extra power Pain Reliever Tablets (PL 12063/0009). No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product which, in turn, has been shown to be interchangeable with the innovator product. Extensive clinical experience with aspirin, paracetamol and caffeine is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.
### STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the marketing authorisation application on 27\textsuperscript{th} January 2009.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 10\textsuperscript{th} February 2009.</td>
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<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 7\textsuperscript{th} May 2009.</td>
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<td>The applicant responded to the MHRA’s requests, providing further information on 21\textsuperscript{st} July 2009.</td>
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<td>The application was determined on 23\textsuperscript{rd} September 2009.</td>
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BOOTS ASPIRIN EXTRA TABLETS/
ASDA/ NUMARK/ PARAMED/ WILKO/ EXTRA POWER PAIN RELIEVER TABLETS/
GALPHARM / LLOYDS/ MORRISONS/ SAINSBURY’S/ TESCO EXTRA POWER PAIN RELIEVER CAPLETS/
SUPERDRUG EXTRA POWER PAIN RELIEVER
PL 16028/0147

GALPHARM / LLOYDS PHARMACY / SAINSBURY’S/ TESCO EXTRA POWER PAIN RELIEVER CAPLETS
PL 16028/0148

STEPS TAKEN AFTER ASSESSMENT

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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Boots Aspirin Extra Tablets
Asda Extra Power Pain Reliever Tablets
Galpharm Extra Power Pain Reliever Caplets
Lloyds Pharmacy Extra Power Pain Reliever Caplets
Morrison Extra Power Pain Reliever Caplets
Numark Extra Power Pain Reliever Tablets
Paramed Extra Power Pain Reliever Tablets
Sainsbury’s Extra Power Pain Reliever Caplets
Superdrug Extra Power Pain Reliever
Tesco Extra Power Pain Reliever Caplets
Wilko Extra Power Pain Reliever Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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</tr>
<tr>
<td>Caffeine</td>
<td>45</td>
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</tbody>
</table>

3 PHARMACEUTICAL FORM
Tablet

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For the treatment of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, influenza, feverishness and feverish colds.

4.2 Posology and method of administration
For oral administration.

Adults and young persons over 16 years: -
1 or 2 tablets every 4 hours as required. Dose not to be taken more frequently than every 4 hours, with a maximum of 6 tablets in 24 hours.

Do not give to children under 16 years, unless specifically indicated (e.g. for Kawasaki’s disease).

Adult dosage is suitable for the elderly.
4.3 Contraindications
Peptic ulceration and those with a history of peptic ulceration; haemophilia; concurrent
anti-coagulant therapy; hypersensitivity to aspirin, paracetamol and/or other constituents; children
under 16 years and when breast feeding because of possible risk of Reye’s Syndrome.

4.4 Special warnings and precautions for use
Hypersensitivity – asthma – aspirin may provoke or worsen asthma.

There is a possible association between aspirin and Reye’s syndrome when given to children.
Reye’s syndrome is a very rare disease, which affects the brain and liver and can be fatal. For this
reason aspirin should not be given to children under 16 years unless specifically indicated (e.g. for
Kawasaki’s disease).

The following warnings will appear on the pack:-

If symptoms persist consult your doctor.
Do not exceed 6 tablets in any 24 hours.
Do not give to children under 16 unless your doctor tells you to.
Keep all medicines out of reach and sight of children.

CONTAINS ASPIRIN AND PARACETAMOL.
Do not exceed the stated dose.
“Do not take any other paracetamol-containing products whilst taking this product” and
“Immediate medical advice should be sought in the event of an overdose, even if you feel well.”
Care is advised in the administration of paracetamol to patients with severe renal or hepatic
impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction
The following are noted, but are unlikely to apply when the product is used for a short-term
symptomatic relief, as directed:-

ASPIRIN

Antacids and Adsorbents: Increase excretion of aspirin in alkaline urine.

Mifepristone: Increased risk of bleeding – avoid use of aspirin for
8-12 days after administration of mifepristone.

Spironolactone: Antagonism of diuretic effect.

Heparin: Increased risk of bleeding.
Phenindione: Increased risk of bleeding.

Warfarin & other coumarins: Increased risk of bleeding.

Domperidone & Metoclopramide: Enhance the effect of aspirin.

Phenytoin & valproate: Enhance the effect of phenytoin and valproate.

Methotrexate: Delayed excretion and increased toxicity of Methotrexate

Uricosurics: Inhibition of uricosurics.

**PARACETAMOL**

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone. Colestyramine may reduce the absorption of paracetamol.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

### 4.6 Pregnancy and lactation

There is clinical and epidemiological evidence of safety of aspirin in pregnancy but it may prolong labour and contribute to maternal and neonatal bleeding, and so is best discontinued in late pregnancy. Aspirin appears in breast milk, and regular high doses may affect neonatal clotting. Not recommended with breast feeding due to possible risk of Reye’s Syndrome as well as neonatal bleeding due to hypoprothrombinaemia. Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding. Caffeine appears in breast milk. Irritability and poor sleeping pattern in the infant have been reported.

### 4.7 Effects on ability to drive and use machines

None Stated.

### 4.8 Undesirable effects

Side effects are mild and infrequent, but there is a high incidence of gastro-intestinal irritation with slight asymptomatic blood loss. Increased bleeding time. Bronchospasm and skin reactions in hypersensitive patients. Aspirin may induce gastro-intestinal haemorrhage, occasionally major. It may precipitate gout in susceptible individuals. Possible risk of Reye’s Syndrome in children.

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been rare reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

### 4.9 Overdose

**PARACETAMOL**

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).
Risk factors
If the patient

a, Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.

Or

b, Regularly consumes ethanol in excess of recommended amounts.

Or

c, Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

SALICYLATES/ASPIRIN

Salicylate poisoning is usually associated with plasma concentrations >350 mg/L (2.5 mmol/L). Most adult deaths occur in patients whose concentrations exceed 700 mg/L (5.1 mmol/L). Single doses less than 100 mg/kg are unlikely to cause serious poisoning.

Symptoms

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.
Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopenia, increased INR/PTT, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

**Management**

Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/kg. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700 mg/L (5.1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

**ASPIRIN**

White powder or crystals soluble in alcohol and slightly soluble in water.

**Mechanism of action/effect:**

Salicylate inhibit the activity of the enzyme cyclo-oxygenase to decrease the formation of precursors of prostaglandin’s and thromboxanes from arachidonic acid. Although many of the therapeutic effects may result from inhibition of prostaglandin synthesis (and consequent reduction of prostaglandin activity) in various tissues, other actions may also contribute significantly to the therapeutic effects.

**Analgesic:**

Produces analgesia through a peripheral action by blocking pain impulse generation and via a central action, possibly in the hypothalamus.

**Anti-inflammatory (non-steroidal):**

Exact mechanisms have not been determined. Salicylates may act peripherally in inflamed tissue probably by inhibiting the synthesis of prostaglandins and possibly by inhibiting the synthesis and/or actions of other mediators of the inflammatory response.

**PARACETAMOL**

**Analgesic:**

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting a prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

**Antipyretic:**

Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.
CAFFEINE

Central nervous system stimulant – Caffeine stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amphetamines.

Analgesia Adjunct:

Caffeine constricts cerebral vasculature with an accompanying decrease in cerebral blood flow and in the oxygen tension of the brain. It is believed that caffeine helps to relieve headache by providing a more rapid onset of action and/or enhanced pain relief with lower doses of analgesic. Recent studies with ergotamine indicate that the enhancement of effect by the addition of caffeine may also be due to improved gastrointestinal absorption of ergotamine when administered with caffeine.

ATC code: R05X

5.2 Pharmacokinetic properties

ASPIRIN

Absorption and Fate

Absorption is generally rapid and complete following oral administration. It is largely hydrolysed in the gastrointestinal tract, liver and blood to salicylate which is further metabolised primarily in the liver.

PARACETAMOL

Absorption and Fate

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 – 4 hours. Plasma-protein is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl cellulose
Maize Starch
Microcrystalline Cellulose
Sorbitol
Sodium Lauryl Sulphate
Hydrogenated Cotton Seed Oil
Methylhydroxypropylcellulose
Polyethylene Glycol 3350

6.2 Incompatibilities

None other than those listed under 4.5 interactions.
6.3 Shelf life
3 years.

6.4 Special precautions for storage
None.

6.5 Nature and contents of container
1. Blister packs of the following construction –

   (i) 250 micron UPVC./20 micron aluminium foil blister.
   (ii) 30 micron pyramidally embossed hard temper aluminium (with 250 micron PVC blisters).
   (iii) 35/9 Paper/Foil with PVC blister.
   (iv) 250 micron PVC lid/Foil 1.0 g/m² lacquer, 20 micron hardened aluminium, seal.

2. Polypropylene drums with HDPE Child Resistant Caps.

The blister packs are packed into boxboard cartons in blister counts of 24 and 32 tablets.

Polypropylene drums of 25 tablets.

6.6 Special precautions for disposal
None.

7 MARKETING AUTHORISATION HOLDER
Galpharm Healthcare Ltd
Upper Cliffe Road
Dodworth Business Park
Dodworth
South Yorkshire
S75 3SP
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)
PL 16028/0147

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
23/09/2009

10 DATE OF REVISION OF THE TEXT
23/09/2009
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Galpharm Extra Power Pain Reliever Caplets
Lloyds Pharmacy Extra Power Pain Reliever Caplets
Sainsbury’s Extra Power Pain Reliever Caplets
Tesco Extra Power Pain Reliever Caplets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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3 PHARMACEUTICAL FORM
Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For the treatment of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, influenza, feverishness and feverish colds.

4.2 Posology and method of administration
For oral administration.
Adults and young persons over 16 years:
1 or 2 tablets every 4 hours as required. Dose not to be taken more frequently than every 4 hours, with a maximum of 6 tablets in 24 hours.
Do not give to children under 16 years, unless specifically indicated (e.g. for Kawasaki’s disease).

Adult dosage is suitable for the elderly.

4.3 Contraindications
Peptic ulceration and those with a history of peptic ulceration; haemophilia; concurrent anti-coagulant therapy; hypersensitivity to aspirin, paracetamol and/or other constituents; children under 16 years and when breast feeding because of possible risk of Reye’s Syndrome.

4.4 Special warnings and precautions for use
Hypersensitivity – asthma – aspirin may provoke or worsen asthma.

There is a possible association between aspirin and Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease, which affects the brain and liver and can be fatal. For this reason aspirin should not be given to children under 16 years unless specifically indicated (e.g. for Kawasaki’s disease).

The following warnings will appear on the pack:-
If symptoms persist consult your doctor.
Do not exceed 6 tablets in any 24 hours.
Do not give to children under 16 unless your doctor tells you to.
Keep all medicines out of reach and sight of children.

**CONTAINS ASPIRIN AND PARACETAMOL.**

Do not exceed the stated dose.

“Do not take any other paracetamol-containing products whilst taking this product” and
“Immediate medical advice should be sought in the event of an overdose, even if you feel well.”

Care is advised in the administration of paracetamol to patients with severe renal or hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

The leaflet shall say “Immediate medical advice should be sought in the event of an overdose, even if you feel/the child seems well, because of the risk of delayed, serious liver damage”.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

### 4.5 Interaction with other medicinal products and other forms of interaction

The following are noted, but are unlikely to apply when the product is used for a short-term symptomatic relief, as directed:-

**ASPIRIN**

Antacids and Adsorbents: Increase excretion of aspirin in alkaline urine.

Mifepristone: Increased risk of bleeding – avoid use of aspirin for 8-12 days after administration of mifepristone.

Spironolactone: Antagonism of diuretic effect.

Heparin: Increased risk of bleeding.

Phenindione: Increased risk of bleeding.

Warfarin & other coumarins: Increased risk of bleeding.

Domperidone & Metoclopramide: Enhance the effect of aspirin.

Phenytoin & valproate: Enhance the effect of phenytoin and valproate.

Methotrexate: Delayed excretion and increased toxicity of methotrexate.

Uricosurics: Inhibition of uricosurics.

**PARACETAMOL**

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone. Colestyramine may reduce the absorption of paracetamol.
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6 Pregnancy and lactation
There is clinical and epidemiological evidence of safety of aspirin in pregnancy but it may prolong labour and contribute to maternal and neonatal bleeding, and so is best discontinued in late pregnancy.

Aspirin appears in breast milk, and regular high doses may affect neonatal clotting. Not recommended with breast feeding due to possible risk of Reye’s Syndrome as well as neonatal bleeding due to hypoprothrombinaemia.

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Caffeine appears in breast milk. Irritability and poor sleeping pattern in the infant have been reported.

4.7 Effects on ability to drive and use machines
None Stated.

4.8 Undesirable effects
Side effects are mild and infrequent, but there is a high incidence of gastro-intestinal irritation with slight asymptomatic blood loss. Increased bleeding time. Bronchospasm and skin reactions in hypersensitive patients. Aspirin may induce gastro-intestinal haemorrhage, occasionally major. It may precipitate gout in susceptible individuals. Possible risk of Reye’s Syndrome in children.

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been rare reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

4.9 Overdose
PARACETAMOL
Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors
If the patient
a, Is on long term treatment with carbamazepine, phenobarbitalone, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.

Or
b, Regularly consumes ethanol in excess of recommended amounts.

Or
c, Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

**Management**

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

**SALICYLATES/ASPIRIN**

Salicylate poisoning is usually associated with plasma concentrations >350 mg/L (2.5 mmol/L). Most adult deaths occur in patients whose concentrations exceed 700 mg/L (5.1 mmol/L). Single doses less than 100 mg/kg are unlikely to cause serious poisoning.

**Symptoms**

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopenia, increased INR/PTT, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

**Management**

Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/kg. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.
Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700 mg/L (5.1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ASPIRIN

White powder or crystals soluble in alcohol and slightly soluble in water.

Mechanism of action/effect:

Salicylate inhibit the activity of the enzyme cyclo-oxygenase to decrease the formation of precursors of prostaglandin’s and thromboxanes from arachidonic acid. Although many of the therapeutic effects may result from inhibition of prostaglandin synthesis (and consequent reduction of prostaglandin activity) in various tissues, other actions may also contribute significantly to the therapeutic effects.

Analgesic:

Produces analgesia through a peripheral action by blocking pain impulse generation and via a central action, possibly in the hypothalamus.

Anti-inflammatoty (non-steroidal):

Exact mechanisms have not been determined. Salicylates may act peripherally in inflamed tissue probably by inhibiting the synthesis of prostaglandins and possibly by inhibiting the synthesis and/or actions of other mediators of the inflammatory response.

PARACETAMOL

Analgesic:

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting a prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Antipyretic:

Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

CAFFEINE

Central nervous system stimulant – Caffeine stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amphetamines.

Analgesia Adjunct:

Caffeine constricts cerebral vasculature with an accompanying decrease in cerebral blood flow and in the oxygen tension of the brain. It is believed that caffeine helps to relieve headache by providing a more rapid onset of action and/or enhanced pain relief with lower doses of analgesic. Recent studies with ergotamine indicate that the enhancement of effect by the addition of caffeine may also be due to improved gastrointestinal absorption of ergotamine when administered with caffeine.

ATC code: R05X
5.2 Pharmacokinetic properties

**ASPIRIN**

**Absorption and Fate**

Absorption is generally rapid and complete following oral administration. It is largely hydrolysed in the gastrointestinal tract, liver and blood to salicylate which is further metabolised primarily in the liver.

**PARACETAMOL**

**Absorption and Fate**

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 – 4 hours. Plasma-protein is negligible at usual therapeautic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl cellulose  
Maize Starch  
Microcrystalline Cellulose  
Sorbitol  
Sodium Lauryl Sulphate  
Hydrogenated Cotton Seed Oil  
Methylhydroxypropylcellulose  
Polyethylene Glycol 3350

6.2 Incompatibilities

None other than those listed under 4.5 interactions.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

1. Blister packs of the following construction –

(i) 250 micron UPVC./20 micron aluminium foil blister.  
(ii) 30 micron pyramidally embossed hard temper aluminium (with 250 micron PVC blisters).
(iii) 35/9 Paper/Foil with PVC blister.
(iv) 250 micron PVC lid/Foil 1.0 g/m² lacquer, 20 micron hardened aluminium, seal.

2. Polypropylene drums with HDPE Child Resistant Caps.

The blister packs are packed into boxboard cartons in blister counts of 24 and 32 tablets.

Polypropylene drums of 25 tablets.

6.6 Special precautions for disposal
None.

7 MARKETING AUTHORISATION HOLDER
Galpharm Healthcare Ltd
Upper Cliffe Road
Dodworth Business Park
Dodworth
South Yorkshire
S75 3SP
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)
PL 16028/0148

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
23/09/2009

10 DATE OF REVISION OF THE TEXT
23/09/2009
PATIENT INFORMATION LEAFLET

Please note that the PILs for PL 16028/0148 are identical to those shown here for PL 16028/0147 except for the PL number.

Asda Extra Power Pain Reliever Tablets
Paracetamol, Aspirin, Codeine
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

The medicine is available with or without prescription, however, you should read the product information carefully to get the best result from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?
   - This medicine contains:
     - Paracetamol, which is a pain reliever (analgesic) and helps reduce fever.
     - Aspirin, which is a pain reliever (analgesic) and helps reduce fever.
     - Codeine, which helps to decrease the pain relief from paracetamol and makes you more alert.

   These tablets are for relief of mild to moderate pain as indicated by headache, migraine, toothache, bone pain, sore throat and period pain. They are also synergistic analgesic agents, stimulants, antipyretics, antihistamines, muscle relaxants and pain, joint swelling and stiffness, tooth decays and bowel colic.

2. Is this medicine suitable for you?
   - Do not take this medicine if you:
     - Are allergic to paracetamol, aspirin or codeine.
     - Have had an adverse reaction to one or more of the ingredients.
     - Have, or have had, a stomach ulcer.
     - Have been told by your doctor or pharmacist that you have a blood clotting disorder.
     - Are pregnant or breast feeding.
     - Are under 16 years old.

   - The following medicines may make this medicine less effective or more harmful:
     - Alcohol.
     - Antidepressants.
     - Antibiotics.
     - Anticonvulsants.
     - Anticoagulants.
     - Antihistamines.
     - Antipsychotics.
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Boots Aspirin Extra Tablets
Paracetamol, Aspirin, Caffeine
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know. This medicine is available without prescription, however, you will still need to use this product carefully as it can get the best results from it. Keep this leaflet as you may need to refer to it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?

This medicine contains:
- paracetamol which is a pain reliever (analgesic) and helps to reduce your temperature when you have a fever
- aspirin which is a pain reliever (analgesic) and helps to reduce swelling
- caffeine which helps to increase the pain relief from paracetamol and makes you more alert.

These tablets are for the relief of mild to moderate pain including headache, migraine, toothache, back pain, and period pain. They are taken for symptomatic relief of sinus, intense facial pain, colds, hay fever, influenza, muscular aches and pains, joint swelling and stiffness, the discomfort and loss of energy.

2. Is this medicine suitable for you?

Do not take this medicine if you:
- are allergic to paracetamol, aspirin, caffeine, or any of the other ingredients
- have a haemoglobin or any other blood clotting disorders
- have had an allergic reaction to analgesics
- are pregnant or breast feeding
- are under 16 years old

If you are taking any of the following medicines please see your doctor:
- medicines to treat high blood pressure which reduce the amount of fluid in the blood such as diuretics
- medicines to control bleeding of a sort such as aspirin, dipyridamole, and clopidogrel
- medicines called anticoagulants which are used to thin the blood such as warfarin and other medicines - you may take occasional doses of paracetamol but you should consult your doctor if you need to take it for a regular basis
- other anti-coagulant medicines such as heparin and anticoagulants
- insulin, used as a treatment for diabetes, such as insulin, or sulfonylurea, such as glibenclamide
- medicines used to control blood coagulation such as aspirin or entacapone
- methotrexate, used for cancer therapy or to treat psoriasis
- salicylates, used to treat heart problems and fluid retention
- medicines to treat gout such as colchicine, allopurinol, probenecid and sulphasalazine
- Cetirizine paracetamol and aspirin.

Do not take with any other paracetamol-containing products.

2. Is this medicine suitable for you? (continued)

Information about some of the ingredients in this medicine:
Cetirizine (4036): If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking the medicinal product.

3. How to take this medicine

Follow the tablet whole with water. Do not chew.
Adults, the elderly and young persons over 16 years: 1 or 2 tablets every 4 hours as required.
Do not take more than 8 tablets in any 24 hour period.
Do not take more than 24 tablets in any 48 hour period.

Do not give to children under 16 years.

There is a possibility of an association between aspirin and Reye's Syndrome when given to children. Reye's Syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.

Do not exceed the stated dose.

If your symptoms persist or worsen, you must see a doctor or pharmacist.

Immediate medical advice should be sought in the event of an overdose, even if you feel well. (Because of the risk of delayed, severe liver damage, go to your nearest hospital casualty department. Take the medicine and this leaflet with you).

4. Possible side effects

Many people do not have any side effects while taking this medicine. However, if you experience any of the following side-effects, stop taking the medicine immediately, stop taking the medicine immediately, and see your doctor or pharmacist:

Rare side effects are:
- allergic type reactions such as skin rash, cough, swelling and tightness of the chest, asthma or wheeze, brought on by aspirin
- bleeding in the stomach or bleeding, which can be seen as black, tarry stools when you go to the toilet or blood in vomit which may look like coffee grounds when you are being sick
- More rarely, the following side effects can happen:
- you may become less able to bleed after a cut or injury
- you may become more prone to bleeding, bruising, and unusual bruising, such as easy, obvious, and unusual bruising, and easy bruising of a cut or injury

5. How to store your medicine

Keep all medicines out of the reach and sight of children.

Do not use this medicine after the expiry date printed on the pack.

6. What is in this medicine?

Each tablet contains the active ingredients paracetamol (325 mg), aspirin (325 mg) and caffeine (80 mg). The other ingredients are: starch, methyl cellulose, microcrystalline cellulose, talc, sodium benzoate, hydroxypropyl methyl cellulose, and propylene glycol.

This product is available in a pack size of 16 tablets.

7. Who makes this medicine?

The Marketing Authorisation holder is GSK Consumer Healthcare Ltd, 2000 Great West Road, Brentford, Middlesex, TW8 9PF. The manufacturer is William Laboratories Ltd, Brentwood, Essex, CM15 8LJ, UK. This product is manufactured by this company.

Please refer to page 28.
Galpharm Extra Power Pain Reliever Caplets/Tablets

Patient Information Leaflet

1. What is this medicine and what is it used for?

This medicine contains:
- Paracetamol which is a pain reliever and helps reduce your temperature when you have a fever.
- Acetaminophen which is a pain reliever (analgesic) and helps to reduce swelling.

This medicine helps to relieve mild to moderate pain for the relief of mild to moderate pain including headaches, migraine, toothache, muscle aches and pains, joint pain, and stiffness, flu, backache and fever.

2. Is this medicine suitable for you?

Do not take this medicine if you:
- are allergic to paracetamol, aspirin, caffeine or any of the other ingredients.
- have, or have ever had, a stomach ulcer.
- have bleeding problems or any other blood clotting disorder.
- are pregnant or breast feeding.
- are under 16 years old.

3. How to take this medicine

Be sure the tablets are safe for use. Do not chew.

Adults, the elderly and young persons over 65 years: 1 or 2 tablets every 4 hours as needed. Do not take more than 8 tablets in any 24-hour period. Do not take more than 4 tablets every 4 hours.

Do not give to children under 16 years. There is a possible association between aspirin and Reye’s syndrome in children. Reye’s syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children under 16 years unless on the advice of a doctor.

Do not exceed the stated dose. If your symptoms persist or worsen, you must see a doctor or pharmacist.

Intermediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, severe liver damage. Go to your nearest hospital casualty department, take the medicine and leaflet with you.

4. Possible side effects

Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else that happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
- Allergies: Swelling such as skin rash, breathlessness, tightening of the chest, high blood pressure, dizziness or fainting, especially when taken with paracetamol, aspirin, caffeine or any of the other ingredients.
- Headache, feeling faint, constipation, depression, diarrhoea, feeling or being sick.
- Confusion, feeling restless, difficult or unusual movements.
- Difficulty in speaking or swallowing.
- Seizures, convulsions.

5. How to store your medicine

Keep all medicines out of the reach and sight of children. Do not use this medicine after the expiry date printed on pack.

6. What is this medicine?

Each tablet contains the active ingredients paracetamol 200 mg, aspirin 325 mg and caffeine 40 mg. The other ingredients are: microcrystalline cellulose, croscarmellose sodium, starch E-15, magnesium stearate, hydroxypropyl cellulose, talc, magnesium stearate, polyethylene glycol 4000.

This product is available in a pack size of 16 tablets.

7. Who makes this medicine?

The Medicine and Healthcare Products Regulatory Agency (MHRA) is authorized to license Galpharm Healthcare Ltd, Dockford, South Yate, Bristol, BS2 8AF, UK. The medicine is supplied by Galpharm Healthcare Ltd, Dockford, South Yate, Bristol, BS2 8AF, UK. The product is also licensed in other countries.

PL 16028/0147-8
Lloyds Pharmacy Extra Power Pain Reliever Caplets/Tablets

Product information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

This medicine is indicated for the treatment of pain and fever in adults, aged 18 years and over.

**1. What is this medicine and what is it used for?**

This medicine contains:

- **Paracetamol** which is a pain reliever
- **Ibuprofen** which is an anti-inflammatory

It should help to reduce your temperature when you have a fever and when you have pain.

**2. Is this medicine suitable for you?**

Do not take this medicine if you:

- are allergic to paracetamol, ibuprofen, or any of the other ingredients
- have had, or had, a serious allergic reaction (e.g. rash, swelling or difficulty in breathing)

- are pregnant or breast feeding

- are under 18 years old

- are taking medicines called antiplatelet agents, such as aspirin, clopidogrel or any other brand of different name

- have stomach ulcers or any other stomach disease

- have problems related to your liver or kidneys

- take a medicine called a proton pump inhibitor (e.g. proton pump inhibitor tablets, such as omeprazole or esomeprazole)

- have a bleeding tendency

**3. How to take this medicine**

Swallow the tablets whole with water. Do not chew.

- Adult doses: the usual adult dose is 2 tablets every 4 hours as required, or 8 tablets a day
- Children aged 10 to 15 years: take 1 tablet every 4 hours as required
- Children aged 4 to 10 years: take 1/2 tablet every 4 hours as required
- Children under 4 years of age: consult a doctor

**4. Possible side effects**

Most people do not have any side effects while taking this medicine. However, if any side effects are noted, please report them to your doctor, pharmacist or by using the reporting system below.

- **Common side effects**
  - Feeling drowsy or dizziness
  - Nausea or vomiting
  - Headache or ringing in the ears
  - Gastrointestinal symptoms (such as indigestion, heartburn, abdominal pain)

- **Rare side effects**
  - **Skin and mouth**
    - Rash, hives, itching
  - **Liver and kidneys**
    - Abnormal liver tests
  - **Blood**
    - Abnormal blood tests

- **Severe side effects**
  - **Skin and mouth**
    - Severe allergic reaction (e.g. anaphylaxis, angioedema, Stevens-Johnson syndrome) with or without fever
  - **Liver and kidneys**
    - Jaundice
  - **Blood**
    - Thrombocytopenia (low platelet count)

**5. How to handle and disposal of waste medicine**

Keep all medicines out of the reach and sight of children. Do not use this medicine after the expiry date printed on the pack.

**6. What is in this medicine?**

Each tablet contains the active ingredients:

- **Paracetamol**: 500 mg
- **Ibuprofen**: 200 mg

**7. Who makes this medicine?**

This medicine is made by

**8. What should I do if you take too much of this medicine?**

In the event of an overdose, seek medical advice immediately by contacting a doctor or the UK Poisons Information Centre.

**9. Additional information**

This medicine is available without prescription.

**10. Further information**

If you have any further questions, please consult your doctor or pharmacist.

**11. How to report suspected adverse reactions**

If you think you have had a side effect from this medicine, please report it. Your doctor or pharmacist will probably already be keeping records of your medicine to help them monitor adverse effects. You can also report it to the MHRA (Medicines and Healthcare products Regulatory Agency) by visiting their website or calling their hotline.

**12. Date of printing**

This leaflet was printed on [insert date].
Morrison's Extra Power Pain Reliever Caplets/Tablets
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know. This medicine is available without prescription; however, you still need to use the product correctly to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?
   This medicine contains:
   - paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever.
   - aspirin which is a pain reliever (analgesic) and helps reduce swelling.
   - caffeine which helps to increase the pain relief from paracetamol and makes you more alert.
   These tablets are for the relief of mild to moderate pain including headache, migraine, toothache, minor pain and fever.

2. Is this medicine suitable for you?
   Do not take this medicine if you:
   - are allergic to paracetamol, aspirin, caffeine or any of the other ingredients.
   - have a liver or kidney problem, a stomach ulcer.
   - have haemoglobin of any other blood donating disorder.
   - are pregnant or breast feeding.
   - are under 16 years old.
   - are taking medicines called anti-coagulants, to stop blood from clotting.
   - have an allergy to any of the ingredients or medicines supplied with this medicine.

   If you are taking any of the following medicines please see your doctor:
   - medicines to treat high blood pressure, which reduce the amount of blood that can enter your body.
   - medicines to control high blood sugar, which reduce the amount of blood that can enter your body.
   - medicines to treat eye problems, which reduce the amount of blood that can enter your body.
   - medicines to treat heart problems, which reduce the amount of blood that can enter your body.

2. Is this medicine suitable for you? (continued)
   Information about some of the ingredients in this medicine.
   Contains ibuprofen (EBL). If you have been told by your doctor that you have an intolerance to one or more of these, please consult your doctor before taking this medicinal product.

3. How to take this medicine
   Follow the tablets when with water. Do not chew.
   Adults. The elderly and young persons over 18 years of age and children 12 years and over take no more than 4 tablets in 24 hours period. Do not take more than this every 4 hours. Do not give to children under 16 years.
   There is a possibility of developing an allergy to aspirin. The symptoms of this allergy include fever and swelling of the face, tongue and throat. If you develop any of these symptoms, stop taking aspirin and consult your doctor without delay. People with this allergy should not be prescribed aspirin.
   The tablets are for the relief of mild to moderate pain and fever.
   Do not exceed the stated dose.
   If you have any of these symptoms, consult a doctor or pharmacist.
   Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of serious, irreversible damage. Go to your nearest hospital casualty department. Take your medicine and the label with you.

4. Possible side effects
   Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.
   Rare side effects are:
   - allergic type reactions such as skin rash, swelling of the face, tongue and throat. Take your medicine and the label with you.
   - bleeding into the stomach or bowel band, which can be seen as black, tarry stools. If you go to the toilet or bowel band, which may look like coffee grounds when you are being sick. If you have any of these symptoms, consult a doctor or pharmacist.
   - unusual bleeding or bruising, change in colour of your urine, these are serious side effects and may be caused by the effects of the medicine on the blood.
   - bleeding into the stomach or bowel band, which can be seen as black, tarry stools. If you go to the toilet or bowel band, which may look like coffee grounds when you are being sick.
   - unusual bleeding or bruising.
   - change in the way that your urine looks.
   - red blood cells or other blood cells may be seen in your urine.

5. How to store your medicine
   Keep medicines out of the reach and sight of children. Do not use this medicine after the expiry date printed on the pack.

6. What is in this medicine?
   Each tablet contains the active ingredients:
   - paracetamol 250 mg, aspirin 250 mg, caffeine 45 mg.
   The other ingredients are maltose, microcrystalline cellulose, starch, povidone, hydroxypropyl methylcellulose, polyethylene glycol and sodium. This product is available in a package of 16 tablets.

7. Who makes this medicine?
   The Marketing Authorisation holder is GlaxoSmithKline Healthcare Ltd, Hoddesdon, London N72 9RE. The manufacturer is: GlaxoSmithKline Healthcare Ltd, Hoddesdon, London N72 9RE. The authorized person responsible for the production of this medicinal product is GlaxoSmithKline Healthcare Ltd, Hoddesdon, London N72 9RE.
   Date Revised: January 2009.
   PL 16028/0147-8
Numark Extra Power Pain Reliever Tablets
Paracetamol, Aspirin, Caffeine
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know. This medicine is available without prescription, however you still need to use the product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you require more information or advice.

1. What is this medicine and what is it used for?

This medicine contains:
- paracetamol which is a pain reliever and helps reduce your temperature when you have a fever
- aspirin which is a pain reliever and helps reduce fever
- caffeine which helps to increase the pain relief from paracetamol and makes you feel more alert.

These tablets are for the relief of mild to moderate pain including headache, migraine, toothache, minor pains, sore throat and period pain. They are also for symptomatic relief of sprains, strains, muscular pain, stiffness, URTI, backache, menstrual pain, chest pain, neuralgia, neuralgia, muscle aches and pains, joint aching and stiffness, toothache and lessening colds.

2. Is this medicine suitable for you?

Do not take this medicine if you:
- are allergic to paracetamol, aspirin, caffeine or any of the other ingredients
- have ever had a stomach ulcer
- have haemorrhoids or any other bleeding disorder
- are pregnant or breast feeding
- are under 16 years old

3. Is this medicine suitable for you? (continued)

Information about some of the ingredients in this medicine:
- Contains paracetamol (E27) if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

4. How to take this medicine

Swallow the tablets whole with water. Do not chew.

Adults, the elderly and young persons over 15 years: 1 to 2 tablets every 4 hours as required. Do not take more than 6 tablets in any 24 hour period. Do not take more than every 4 hours.

Children under 16 years:
- There is a possible association between paracetamol and Reye's Syndrome when given to children.
- Reye's Syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.

Do not exceed the stated dose. If your symptoms persist or worsen, you must see a doctor or pharmacist. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

5. Possible side effects

Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

- are taking medicines called anti-coagulants, to stop your blood from clotting,
- please see your doctor or pharmacist before taking this medicine if you:
- suffer from liver or kidney problems, including alcoholic liver disease
- have asthma
- have an intolerance to some sugars.

If you are taking any of the following medicines please see your doctor:
- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as statins
- medicines to control existing high blood pressure such as methyldopa or bendroflumethiazide
- medicines called anti-coagulants, which are used to thin the blood such as warfarin and other oral anticoagulants.

6. How to store your medicine

Keep all medicines out of the reach and sight of children.

Do not use this medicine after the expiry date printed on the pack.

7. What is in this medicine?

Each tablet contains the active ingredients:
- paracetamol 200 mg, aspirin 360 mg and caffeine 60 mg.
- The other ingredients are: sodium starch, sodium carboxymethylcellulose, soda aluminas, sodium lauryl sulphate, hydroxypropyl methyl cellulose and polyethylene glycol.

This product is available in a pack size of 16 tablets.

MHRA-UKPAR – Extra power Pain Reliever Caplets/Tablets

PL 16028/0147-8
Paramed Extra Power Pain Reliever Tablets
Paracetamol, Aspirin, Caffeine
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

This medicine is available without prescription, however, you still need to use this product carefully to get the best results. It is important that you keep this leaflet so you need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?
This medicine contains:
- Paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever.
- Aspirin which is a pain reliever (analgesic) and fever reducer.
- Caffeine which helps to increase the pain relief from paracetamol and makes you feel more alert.

These tablets are for the relief of mild to moderate pain including headache, migraine, toothache, nausea, sore throat and period pains. They are also for symptomatic relief of pain, stiffness, inflammation, pain, swelling, redness and fever. They are also used to reduce nausea and vomiting.

2. Is this medicine suitable for you?
Do not take this medicine if you:
- are allergic to paracetamol, aspirin, caffeine or any of the other ingredients.
- have, or have ever had, a stomach ulcer.
- have haemophilia or any other blood clotting disorder.
- are pregnant or breast feeding.
- are under 16 years old.
- are taking medicines called anti-coagulants, to stop your blood from clotting.

Please see your doctor or pharmacist before taking this medicine if you:
- suffer from kidney or liver problems, including alchoholic disease
- have asthma.
- have an intolerance to some sugars.

If you are taking any of the following medicines please see your doctor:
- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as clofibrate.
- medicines to control feeling sick or being sick such as metoclopramide or domperidone.
- medicines called anti-coagulants, which are used to thin the blood such as warfarin and other benzodiazepines - you may take occasional doses of paracetamol but should consult your doctor if you are prescribed this by another doctor.
- other anti-coagulants medicines such as heparin and coumadin.
- antidepressants, used as a treatment for depression, such as paroxetine, sertraline, citalopram and escitalopram.
- medicines used to control seizures in epilepsy such as phenytoin or sodium valproate.
- medicines used to treat cancer therapy or to treat problems.
- metoclopramide.
- spironolactone, used to treat heart disease and fluid retention.
- medicines to treat gout such as colchicine, allopurinol, probenecid and sulfinpyrazone.
- Contains paracetamol and aspirin.
- Do not take with any other painrelieving or anti-inflammatory products.

Please turn over.

2. Is this medicine suitable for you? (continued)

Information about some of the ingredients in this medicine:
Contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take this medicine
Read the tablets whole without breaking or chewing. Adults, the elderly and young persons over 14 years: 1 or 2 tablets every 4 to 6 hours as required. Do not take more than 8 tablets in any 24-hour period. Do not take more than 4 tablets every 4 hours. Do not give to children under 16 years. There is a possible association between aspirin and Reye's Syndrome when given to children. Reye's Syndrome is a very rare disease which can be fatal. For this reason aspirin should not be given to children under 16 years, unless the advice of a doctor.

Do not exceed the stated dose. If your symptoms persist or worsen, you must see a doctor or pharmacist.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4. Possible side effects
Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
- allergic type reactions such as skin rash, cough, wheezing and tightness of the chest.
- asthma or breathing difficulty.
- bleeding in the stomach or blood tinged which can be seen as dark, black, tarry stools when you go to the toilet or blood in vomit which may look like coffee grounds when you are being sick.

More rarely, the following side effects can happen:
- you may take longer to stop bleeding after a cut.
- you may become more prone to bleeding.
- stools, urine and sweat, such as those from the skin.

5. How to store your medicine
Keep all medicines out of the reach of children.

Do not use this medicine after the expiry date printed on the pack.

6. What is in this medicine?
Each tablet contains the active ingredients:
- Paracetamol 250 mg
- Aspirin 360 mg
- Caffeine 40 mg
- Other ingredients are: starch, maize starch, microcrystalline cellulose, sorbitol (E420), sodium lauryl sulphate, hydroxypropyl methylcellulose, triacetin, titanium dioxide and polyethylene glycol.

This product is available in a pack size of 16 tablets.

7. Who makes this medicine?
Sainsbury’s Extra Power Pain Reliever Caplets
Paracetamol, Aspirin, Caffeine
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

This medicine is available without prescription; however, you should use this product carefully to get the best results and to keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?

This medicine contains:
- paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- aspirin which is a pain reliever (analgesic) and helps to reduce swelling
- caffeine which helps to increase the pain relief from paracetamol and makes you more alert.

These tablets are for the relief of mild to moderate pain including headache, migraine, backache, neuralgia, period pain and toothache. They are also helpful in mild cases of sprains, strains, muscular aches and pains. Joint swelling and stiffness, rheumatism and kidney colic.

2. Is this medicine suitable for you?

Do not take this medicine if you:
- are allergic to paracetamol, aspirin, caffeine or any of the other ingredients.
- have, or have ever had, a stomach ulcer.
- have any medicines or any other blood clotting disorder
- are pregnant or breastfeeding
- are under 16 years old

- are taking medicines called anticoagulants, to stop your blood from clotting.

Please see your doctor or pharmacist before taking this medicine if you:
- suffer from kidney or liver problems, including alcohol liver disease
- have asthma
- have an imbalance in some organs.

If you are taking any of the following medicines please see your doctor:
- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as statins
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as aspirin and other oral anticoagulants
- medicines used to control stomach ulcers such as proton pump inhibitors or sucralfate
- medicines used to treat heart disease such as beta-blockers, angiotensin converting enzyme inhibitors, angiotensin receptor blockers
- medicines used to treat high blood pressure
- medicines used to treat high cholesterol levels such as statins, and either or both of the following:
- medicines for diabetes, asthma, mental health conditions, other medical conditions
- medicines for high cholesterol levels.

3. How to take this medicine

Swallow the tablet with water. Do not chew.

Adults and the elderly and young persons over 16 years: 1 tablet or 2 tablets every 4 hours as required. Do not take more than 6 tablets in any 24 hour period. Do not take more than 8 tablets in any 24 hour period. Do not give to children under 16 years.

There is a possible association between aspirin and Reye’s Syndrome when given to children. Reye’s Syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.

Do not exceed the stated dose. If you are unsure about the dose, you must see a doctor or pharmacist.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4. Possible side effects

Most people do not have any side effects while taking this medicine. However, try to experience any of the following side effects, or anything else that happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
- allergic reactions such as skin rash, cough, wheezing and tightness of the chest
- a sense of feeling of being ill or faint
- bleeding in the stomach or bowel, which can be seen as dark, tarry stools or blood in the toilet or blood in the vomit, which may look like coffee grounds when you are using the toilet

More rarely, the following side effects can happen:
- you may take longer to stop bleeding after a cut or injury
- you may become more prone to bleeding, bruising, nose bleeds, and cuts
- you may have increased risk of bleeding, bruising, nose bleeds, and cuts
- you may have increased risk of bleeding, bruising, nose bleeds, and cuts

5. How to store your medicine

Keep all medicines out of the reach of children and pets.

Do not use this medicine after the expiry date printed on the pack.

6. What is in this medicine?

Each tablet contains the active ingredients paracetamol 500mg, aspirin 300mg and caffeine 245mg. The other ingredients are: maize starch, polyethylene glycol, hydroxypropyl cellulose, maize starch, polyethylene glycol, hydroxypropyl cellulose, maize starch, polyethylene glycol, hydroxypropyl cellulose, maize starch, polyethylene glycol, hydroxypropyl cellulose, maize starch, polyethylene glycol, hydroxypropyl cellulose

This product is available in a pack size of 16 tablets.

7. Who makes this medicine?

The Marketing Authorization holder is Cipla Healthcare Ltd, DODDING, SOUTH YORKSHIRE S75 3BP. The manufacturer is Whitham Laboratories Ltd, Whitham Drive, EC35 2ZD, UK. Text Revised: January 2009.

PL 16028/0147-8
Superdrug Extra Power Pain Reliever
Paracetamol, Aspirin, Caffeine
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

This medicine is available without prescription; however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?

This medicine contains:
- paracetamol, which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- aspirin, which is a pain reliever (analgesic) and helps reduce swelling
- caffeine, which helps to increase the pain relief from paracetamol and makes you more alert.

These tablets are for the relief of mild to moderate pain including headache, migraine, backache, new pains, joint pain, and period pains. They are also supplied as extended-release tablets to provide pain relief for longer periods.

2. Is this medicine suitable for you?

Do not take this medicine if you:
- are allergic to paracetamol, aspirin, caffeine or any of the other ingredients
- have ever had a stomach ulcer
- have gangrene or any other blood clotting disorder
- are pregnant or breast-feeding
- are under 16 years old
- are taking medicines called anti-coagulants, to stop your blood from clotting.

Please see your doctor or pharmacist before taking this medicine if you:
- suffer from kidney or liver problems, including diabetic liver disease
- have asthma
- have an intolerance to some sugars.

If you are taking any of the following medicines, please see your doctor:
- medicines to treat high blood pressure which may affect the amount of salt in your blood, such as diuretics
- medicines to control blood sugar levels, such as metformin
- some heart medicines, such as warfarin
- certain medicines, such as salicylates
- medicines to control blood fats, such as niacin
- medicines to control blood pressure, such as clonidine
- medicines to treat HIV/AIDS, such as ritonavir
- medicines to treat gout or arthritis, such as corticosteroids (steroids)
- medicines to treat high blood pressure or relaxation

3. How to take this medicine

Swallow the tablets whole with water. DO NOT CHEW.

Adults, the elderly and young persons over 19 years: 1 or 2 tablets every 4 hours as required. Do not take more than 6 tablets in any 24-hour period. Do not take more often than every 4 hours.

Do not give tablets to children under 16 years.

There is an increased risk of bleeding or bruising if you take aspirin or other anti-inflammatory medicines. If you have previously taken aspirin or other anti-inflammatory medicines, you may need to take lower doses of this medicine.

4. Possible side effects

Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately and see your doctor or pharmacist:

Rare side effects are:
- allergic type reactions such as skin rash, itching, swelling of the face, neck, throat, or mouth
- diarrhoea, indigestion, vague abdominal pain
- bleeding in the stomach or bowel. This can be quite serious and may be treated with medicines to stop bleeding
- vomiting, heartburn, or difficulty swallowing
- stomach pain, indigestion

Other side effects include:
- irritability
- headache
- nail changes
- rash
- dizziness
- tiredness
- dry mouth
- nose bleeds
- weakness
- brief loss of vision
- ringing in the ears
- change in colour of a blister
- peeling or blistering

5. How to store your medicine

Keep medicines out of the reach of children.

Do not use this medicine after the expiry date printed on the pack.

6. What is this medicine?

Each tablet contains the active ingredients:
- paracetamol 250 mg
- aspirin 300 mg
- caffeine 45 mg

The other ingredients are:
- starch, cornstarch, hydroxypropyl cellulose, sodium carboxymethyl cellulose, colloidon (E423), sodium lauryl sulphate, hypromellose, talc, magnesium stearate, hydroxypropyl cellulose, polyethylene glycol 6000.

This product is available in a pack of 16 tablets.

7. Who makes this medicine?

The Marketing Authorisation Holder is GlaxoSmithKline Healthcare Limited, Woodford, Bury St Edmunds, Suffolk. UK.

GlaxoSmithKline Healthcare Limited, Woodford, Bury St Edmunds, Suffolk. UK.

Date of Revision: February 2002.
Wilko Extra Power Pain Reliever Tablets
Paracetamol, Aspirin, Caffeine
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine. Because it contains important information you need to know.

This medicine is available without prescription, however, you should not use this product carelessly. It may give misleading results if used incorrectly. Keep this leaflet as you may need to read it again. Ask your pharmacist for more information or advice.

1. What is this medicine and what is it used for?
This medicine contains:
- Paracetamol which is a pain reliever that helps reduce your temperature when you have a fever.
- Aspirin which is a pain reliever that helps to reduce pain and fever.
- Caffeine which helps to increase the pain relief from paracetamol and makes you more alert.

These tablets are for the relief of mild to moderate pain. They may relieve headache, toothache, backache or rheumatic pain. They are also for symptoms of colds, flu, body aches, and pains, joint aching and stiffness, and toothache.

2. Is this medicine suitable for you?
Do not take this medicine if you:
- Are allergic to paracetamol, aspirin, caffeine or any of the other ingredients.
- Have, or have ever had, a stomach ulcer.
- Have a history of peptic ulcer or any other bleeding disorder.
- Are pregnant or breast feeding.
- Are under 16 years old.

- Are taking medicines called anticoagulants, to stop your blood from clotting. Please see your doctor or pharmacist before taking this medicine if you:
- Have allergies to any of the ingredients in this medicine.
- Have asthma.
- Have an intolerance to some sugars.

If you are taking any of the following medicines please see your doctor:
- Medicines to treat high blood pressure, which may increase the amount of harm to your blood vessels and risk of bleeding such as anticoagulants.
- Medicines to control feeling sick or feeling bad, such as antiemetics or domperidone.
- Medicines called anticonvulsants, which are used to treat epilepsy.

3. How to take this medicine
Swallow the tablets whole with water. Do not chew.

Adults, elderly and young persons over 16 years: take 1 or 2 tablets every 4 hours as needed. Do not take more than 8 tablets in any 24-hour period. Do not take more than 4 tablets every 4 hours.

Do not give to children under 16 years. There is a possible association between aspirin and Reye's Syndrome when given to children. Reye's Syndrome is a very rare disease, which can also be fatal. For this reason the medicine should not be given to children aged under 16 years, unless on the advice of a doctor.

Do not exceed the stated dose. If you get any other bad effects, please see a doctor or pharmacist.

4. Possible side effects
Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, any feeling unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist:

- Allergic type reactions such as skin rash, itching, and tightness of the chest.
- Shaking or trembling, dizziness or indigestion.
- Fainting or feeling weak, sweating.
- Feeling tired or listless.
- Blurred vision.
- Swelling.
- Abdominal pain, nausea, vomiting, or diarrhea.
- Swellings or pains in the legs or arms.
- More rarely, the following side effects can happen:
- You may become more prone to bleeding.
- You may become more prone to bleeding.
- You may become more prone to bleeding.
- Changes or discomfort in your blood.

5. How to store your medicine
Keep all medicines out of the reach and sight of children.

6. What is this medicine?
Each tablet contains:
- Paracetamol 200 mg, aspirin 300 mg and caffeine 45 mg.

This product is available in a pack size of 16 tablets.

7. Who makes this medicine?
The Marketing Authorisation holder is Wilko Healthcare Ltd., Tadcaster, North Yorkshire, LS24 9JJ. The manufacturer is Wilko Healthcare Ltd., Tadcaster, North Yorkshire, LS24 9JJ. The manufacturer is Wilko Healthcare Ltd., Tadcaster, North Yorkshire, LS24 9JJ. The manufacturer is Wilko Healthcare Ltd., Tadcaster, North Yorkshire, LS24 9JJ.
LABELLING

Please note that the labels for PL 16028/0148 are identical to those shown here for PL 16028/0147 except for the PL number.