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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.
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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
Morrison’s 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.
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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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 27th January 2009.</td>
</tr>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 10th February 2009.</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 7th May 2009.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 21st July 2009.</td>
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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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EXTRA POWER PAIN RELIEVER CAPLETS/
SUPERDRUG EXTRA POWER PAIN RELIEVER
PL 16028/0147

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
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<tr>
<td>Aspirin</td>
<td>300</td>
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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, 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 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 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
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3 PHARMACEUTICAL FORM
Tablet

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4.1 Therapeutic indications
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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.

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The following warnings will appear on the pack:-
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**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, 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/PT, 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-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 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 amfetamines.

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 pyramidal 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 suitable with your prescription, however, you must read the product information carefully to get the most benefit from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you have any questions or address.

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 in fever.
- aspirin which is a pain reliever (analgesic) and helps reduce swelling.
- codeine which helps to increase the pain relief bar and makes you feel alert.

These tablets are for the relief of mild to moderate pain due to headache, migraine, toothache, bone pain, sore throat and period pain. They are also used to relieve the symptoms of sinusitis, asthma, rhinitis, otitis media, bronchitis, haematuria, colds and flu, muscular aches and pain, joint swelling and stiffness, heartburn and indigestion.

2. Is this medicine suitable for you?

Do not take this medicine if you:

- are allergic to paracetamol, aspirin, codeine 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.

- are taking medicine called anti-coagulants, to stop your blood from clotting. Please see your doctor or pharmacist before taking this medicine.
- have liver failure.
- have serious heart disease.
- have low blood pressure.
- have taken aspirin in the last 14 days.

3. How to take this medicine

Swallow the tablets whole with water. Do not chew.

Adults and the elderly: take 1 to 2 tablets every 4 hours or as required. Do not take more than 8 tablets in any 24 hour period. Do not take more than 24 tablets over a week.

Do not give to children under 16 years. There is a potential for harm, especially with R.S. and L.S. and other heparin, given to children. If you are pregnant, it is a certain disease, which can be caused by a reaction with aspirin. This means aspirin should not be given to children aged 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 medication with you if possible.

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 which makes you feel unusual, stop taking the medicine immediately, and see your doctor or pharmacist.

- are taking medicine called anti-coagulants, to stop your blood from clotting.
- have heart failure.
- have serious heart disease.
- have low blood pressure.
- have taken aspirin in the last 14 days.

4. What can I do if you feel bad?

If you feel bad, stop taking the tablets and contact your doctor or pharmacist.

5. How to store this 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 200 mg,
- aspirin 200 mg,
- codeine phosphate 15 mg.

The other ingredients are:

- polyethylene glycol 4000,
- methyl cellulose,
- gum arabic,
- sodium lauryl sulphate,
- hydroxypropyl methyl cellulose,
- liquorice.

This product is available in a pack size of 10 tablets.

7. Who makes this medicine?

The Marketing Authorisation holder is: GlaxoSmithKline Healthcare Ltd, Cheadle, Cheshire, WA5 5UP. This marketing authorisation is administered by the Medicines and Healthcare products Regulatory Agency (MHRA). Distributed by Baxart Medical Limited, Crawley, West Sussex, RH10 9QW. Revised: January 2006.
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 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 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 awake.

These tablets can be used for the relief of mild to moderate pain including headache, migraine, toothache, back pain, knee pain, sore throat and period pain. They are taken for symptomatic relief of arthritis, muscle, joint and sciatic pain, neck pain, backache, tennis elbow, frozen shoulder, rheumatism, muscle, leg and joint pain, period pain, and stiffness, particularly in the morning.

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.
- are under the age of 16 years old.
- have haemorrhages or any other blood clotting disorder.
- are pregnant or breast feeding.

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

Adults: Take 2 tablets every 4 hours as required. Do not take more than 8 tablets in any 24 hour period. Do not take more than 12 tablets in any 48 hour period.

Children: Take 1 tablet every 4 hours as required. Do not exceed the stated dose. 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.

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 this medicine immediately, and see your doctor or pharmacist:
- unusual sensitivity to light.
- unusual tiredness.
- unusual bleeding from nose or gums.
- unusual bruising or swelling.
- unusual blood in urine.
- unusual blood in stools.
- any allergic reactions.

Rare side effects are:
- breathing difficulty.
- convulsions.
- numbness.

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

6. What is in this medicine?
Each tablet contains the active ingredients:
- Paracetamol 500mg
- Aspirin 300mg
- Caffeine 50mg

7. Who makes this medicine?
The Medicine and Healthcare products Regulatory Agency is the Great Britain's government agency responsible for protecting and promoting the health of the public by ensuring that medicines and medical devices work and are safe to use. The manufacturer is Boots Healthcare Limited, Batchelor's Cross, Bicester, Oxfordshire, OX25 3LR, United Kingdom.

MHRA-UKPAR Extra power Pain Reliever Caplets/Tablets - 28 -
PL 16028/0147-8
Galpharm 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 should only use this product unless you 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
- 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 caplets are used for the relief of mild to moderate pain in conditions such as headache, toothache, backache, period pain, sore throat and period pains. They are also for symptomatic relief of sprains, strains, muscular aches and pains, joint swelling and stiffness, flu, rhinitis and stomach upsets.

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 breastfeeding.

Around 16 years old

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

Information about some of the ingredients in this medicine:
- Contains tartrazine (E102). If you have been told by your doctor that you have an allergy to some sugars, contact your doctor before taking this medicinal product.

3. How to take this medicine

Swallow the tablets whole with water. Do not chew.

Adults, the elderly and young adults over 65 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 than 12 tablets every 24 hours.

Do not give to children under 16 years. There is a possible association between aspirin and Reye’s syndrome in children under the age of 16, 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.

Intravenous 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 your 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 happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
- Allergic reactions such as skin rash, itching or swelling of the face, lips or tongue, breathlessness, mouth or throat swelling or difficulty in swallowing.
- Pain, nausea, vomiting, diarrhoea, abdominal pain or discomfort.
- Nervousness, irritability, restlessness, dizziness, confusion or mood changes.
- Drowsiness, depression, anxiety or agitation.
- Unusual tiredness or weakness.
- Headache.
- Changes in vision or hearing.
- Blood in the urine.
- Blood in the stools.
- Difficulty in breathing.
- Coughing up blood.
- Pain in the chest.
- Severe irregular heartbeat.
- Severe constipation.

See page 27 for a full list of side effects.

5. How to store your medicine

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

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

6. What is in this medicine?

Each tablet contains the active ingredients Paracetamol 200 mg, Aspirin 325 mg and Caffeine 40 mg. The other ingredients are maize starch, microcrystalline cellulose, sodium starch glycollate, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate and colloidal silicon dioxide, polyethylene glycol 4000.

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

7. Who makes this medicine?

The Medicine Authority holds the licence with: Captain Healthcare Ltd., Goddards, South Yorkshire S75 2BN. The manufacturer is: Weihe Laboratories Ltd., Hampton, Dagenham, Essex, IG 8 2LL, UK.

Text Updated: January 2000

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

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 correctly. If you do not use this product correctly and as directed, you may be harmed.

1. What is this medicine and what is it used for?
   This medicine contains:
   - paracetamol which is a pain reliever and fever reducer
   - codeine phosphate which is a pain reliever analgesic and helps to reduce coughing
   - caffeine which can increase the absorption of the paracetamol and makes you more alert.

   These ingredients help to relieve and moderate pain, reduce fever and cough. They are also effective for the relief of mild to moderate pain, headaches, migraine, muscle aches, period pain, sore throat, coughing and cold symptoms. It is not suitable for children.

2. Is this medicine suitable for you?
   Do not take this medicine if you:
   - are allergic to paracetamol, codeine, caffeine or any of the other ingredients.
   - have, or have had, a blood disorder.
   - have liver problems or any other liver disease.
   - are pregnant or breast feeding.
   - are under 16 years old.
   - are taking medicines that you have been prescribed to stop bleeding.
   - have had or are likely to have had bleeding disorders.
   - are taking other medicines that may interact with paracetamol.
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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 should buy 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 to reduce swelling
- Caffeine which helps to increase the pain relief from paracetamol and makes you more alert.

These tablets are one of the most effective pain relievers, including headache, migraine, rheumatism, nerve pain, sinus and tooth pain. They are also for symptomatic relief of sprains, strains, musculoskeletal pain, colds, flu, neuralgia, backache, and pain, fatigue and aches.

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 haemophila 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.
- Are taking medicines called anti-coagulants, which are used to thin the blood such as warfarin and other medications.

- Are taking medicines called anti-coagulants, which are used to thin the blood such as warfarin and other medications.
- Are taking medicines called anti-coagulants, which are used to thin the blood such as warfarin and other medications.
- Are taking medicines called anti-coagulants, which are used to thin the blood such as warfarin and other medications.

3. How to take this medicine

- adults, the elderly and young persons over 16 years: 1 tablet every 4 hours as required.
- Do not exceed more than 6 tablets in 24 hour period.
- Do not take more than the 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.

4. Possible side effects

- Rare side effects are:
  - Allergic type reaction such as rash, swelling, itching of the head
  - Coughing, breathing difficulty, cramps
  - Blotching, itching, swelling, or hives
  - Rash, blisters, red spots, or skin irritation

- If you have any side effects that worry you do not 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 this medicine and the leaflet with you.

5. How to store your medicine

- In a tight container.
- Keep 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.
  - Aspirin 160 mg.
  - Caffeine 45 mg.

- Other ingredients are:
  - Microcrystalline cellulose, colloidal silicon dioxide, crospovidone, magnesium silicate, hypromellose, sodium lauryl sulphate.

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

7. Who makes this medicine?

The Marketing Authorisation holder is GlaxoSmithKline Healthcare Ltd, Codworth, Southbridge, Didcot, Oxon OX11 7DD. The manufacturer is Winthrop Laboratories Ltd, Braintree, Essex CM77 7DL, UK.

Text 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 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
• aspirin which is a pain reliever
• each which helps reduce your body's natural response to injury or illness
• caffeine which helps decrease the pain relief from paracetamol and makes you more alert.
These tablets are for the relief of:
• moderate pain from headache, migraine, toothache
• fever or body aches
• cold or flu
• other minor aches and pains

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 severe liver disease
• have a known allergy to any blood clotting disorder
• are pregnant or breast feeding

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

Adults:
Do not exceed the stated dose. If you take more than 6 tablets a day, contact your doctor for advice.

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

Adults:
Do not exceed the stated dose. If you take more than 6 tablets a day, contact your doctor for advice.

Children:
Do not exceed the stated dose. If you take more than 6 tablets a day, contact your doctor for advice.

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, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
• allergic reactions such as rash, itching, or swelling of the face, tongue, or throat
• sensitivity reactions which may cause skin reactions such as rash, itching, or swelling of the face, tongue, or throat
• dizziness, headache, or feeling faint
• difficulty breathing or wheezing
• unusual bleeding or bruising

5. How to store your medicine
Keep all medicines out of the reach of children.
Store in a cool place.

6. What is in this medicine?
Each tablet contains:
• paracetamol 500 mg
• aspirin 325 mg
• caffeine 72 mg

7. Who makes this medicine?
The Marketing Authorisation holder is Numark Healthcare Ltd., Cradock Lane, Salford M3 8DH, UK.

If you have any further questions, please consult your doctor or pharmacist.
Paramed Extra Power Pain Reliever Tablets
Paracetamol, Aspirin, Caffeine

Read all of this leaflet carefully before you take this medicine because it contains important information about its use.

This medicine is supplied without prescription; however, you must read the leaflet before you take the product.

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 pain and 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, neuralgia, limb pain, rheumatic pain, sciatica, lumbago, iliotibial band, muscular aches and pains. Joint swelling and stiffness, lumbosacral and heurthritis.

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.
- you have ever had a stomach ulcer, have haemorrhoids or any other blood clotting disorder.
- you are pregnant or breast feeding.
- you are under 16 years old.

Do not take:
- medicines called anticoagulants, to stop your blood from clotting.
- blood thinners, or any other medicine that may affect your blood clots.
- medicinal products containing aspirin or paracetamol.
- medicinal products containing caffeine or any other medicine that may affect your blood clots.

Please speak to your doctor or pharmacist on the telephone before taking the medicinal product.

3. How to take this medicine

Swallow the tablets whole with water. Do not chew.

Adults, the elderly and young persons over 16 years: 1 tablet every 4 hours as required. Do not take more than 6 tablets in any 24 hour period. Do not take more than 4 tablets every 4 hours.

Do not give to children under 16 years.

Rarer side effects:
- allergic type reactions such as rash, cough, wheezing and tightness of the chest.
- aphasia or slurred speech.
- breathing difficulty, which can be fatal. For this reason aspirin should not be given to children under 16 years, unless in the advice of a doctor.

Do not exceed the stated dose.

If you feel unwell, you must see a doctor immediately.

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, immediately stop taking the medicine and seek medical advice.

5. What is in this medicine?

Each tablet contains the active ingredients:
- Paracetamol 200 mg.
- Aspirin 360 mg.
- Caffeine 45 mg.

Other ingredients:
- Maltodextrin, microcrystalline cellulose, sorbitol (E420), sodium lauryl sulphate, hydroxypropyl methylcellulose and citric acid.

6. How to store this medicine

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

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

7. Who makes this medicine?

The Marketing Authorisation Holders are Salurn Healthcare Ltd., Codruin, South Bolton, S78 1TF. The manufacturer is Wadham Laboratories Ltd., Brutton, Davy, G75 20L, UK

MHRA-UKPAR –Extra power Pain Reliever Caplets/Tablets

PL 16028/0147-8 - 33 -
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 not use this product unless you are told to do so. 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, toothache, pains in the muscles and joints. They are also helpful in conditions of sprains, strains, muscular aches and pains, joint swelling and stiffness, colds, feverishness, and liver ailments.

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 blood clotting disorder
- are pregnant or breast feeding
- are under 16 years old

- are taking medicines called anti-coagulants, to stop your blood clotting.

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

If you are taking any of the following medicines please see your doctor:
- medicines to lower high cholesterol which reduce the amount of fat in the blood such as colesteplant
- medicines to control lasting sick or feeling sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin and other anti-coagulants - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- other anti-coagulant medicines such as heparin and warfarin

- anti-emetics, used to stop sickness, such as ondansetron or promethazine
- medicines used to control stomach acid or such as paracetamol such as antacids or sodium bicarbonate
- medications, used to treat cancer therapy or to treat infections

- anti-fungal
- antihistamines, used to treat skin diseases and allergies
- medicines to block guilt such as cetirizine, albuterol, prednisolone and sulphamethoxazole
- contains 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:

Paracetamol is metabolized (it is broken down) in the liver and the kidneys, and can cause liver damage when taken in too high a dose. People with liver disease or who take other drugs that can damage the liver should not exceed the recommended dose.

Aspirin can cause an allergic reaction in some people. If you experience any reaction to aspirin, you should not take this medicine.

Caffeine can cause side effects in some people, such as restlessness, nervousness, upset stomach, or diarrhea.

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

Adults and elderly people over 16 years: 1 tablet 1-2 tablets every 4 hours as required. Do not take more than 6 tablets in any 24-hour period. So do not take more than 10 tablets in any 48-hour period. Do not give to children under 16 years.

There is a possibility of associations 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 18 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.

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 you are unsure about, stop taking the medicine immediately, and see your doctor or pharmacist.

RARE side effects are:
- skin rashes such as acne, fever, skin peeling or erosion, itching or irritation of the skin
- lactic acidosis
- bleeding in the stomach or bowel lining, which can cause severe abdominal pain which may cause a fit or convulsion which may cause death if left untreated. It may occur with use of aspirin in high dosage for up to 1 week, with long-term use or in children
- shortness of breath or swelling of the limbs
- shortness of breath or swelling of the limbs

More rarely, the following side effects can happen:
- you may have to stop a long-term course of this medicine due to side effects.
- you may experience more problems with bleeding, bruising, pain and tiredness, such as severe headache, seizures, and weakness.
- you may experience more problems with bleeding, bruising, pain and tiredness, such as severe headache, seizures, and weakness.

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

Do not use after the date of expiry shown on the package.

6. What is this medicine?
Each tablet contains the active ingredients:
- paracetamol 500 mg
- aspirin 300 mg
- caffeine 200 mg
The other ingredients are:
- lactose monohydrate
- sodium starch glycolate
- magnesium stearate
- hydroxypropyl cellulose
- titanium dioxide
- polyethylene glycol

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

7. Who makes this medicine?

PL 900004/01-7
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 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, new pains, sore throat and period pain. They are also of symptomatic relief of sprains, strains, muscle pain, sciatica, backache, arthritis, muscular aches and pain, joint swelling and stiffness, bruising and livid marks.

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 peptic ulcers 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.

3. How to take this medicine
Swallow the latest tablet with water, CAUTION:
Adults, the elderly and young persons over 15 years: 1 or 2 tablets every 3–4 hours as required. Do not take more than 10 tablets in any 24-hour period. Do not take more than 8 tablets every 4 hours. Do not give to children under 16 years.
There is a possible association between aspirin and Raynaud’s Syndrome in children, which is a 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 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:
• allergic type reactions such as skin rash, swelling of the limbs, or breathing difficulty
• bleeding from the stomach or bowel
• bleeding from a wound
• redness of the face or body
• bloody or black vomit
• convulsions
• fits

4. Possible side effects
Most people do not have any side effects when 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:

Side effects:
• headache
• dizziness
• feeling generally unwell
• feeling sluggish
• feeling sleepy
• feeling tired or weak
• feeling dizzy
• feeling faint
• feeling anxious
• feeling irritable
• feeling restless
• feeling nervous
• feeling faint
• feeling dizzy
• feeling tired or weak
• feeling sleepy
• feeling generally unwell
• feeling sluggish
• feeling anxious
• feeling irritable
• feeling restless
• feeling nervous

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 500 mg, aspirin 325 mg and caffeine 45 mg. The other ingredients are: starch, sugar, colloidal silicon dioxide, lactose, magnesium stearate, talc and hypromellose.
This product is available in a pack size of 10 tablets.

7. Who makes this medicine?
The Marketing Authorisation Holder is: GlaxoSmithKline Consumer Healthcare Limited, Brentwood, Essex, CM13 1RP, U.K.
Toll Free: 0800 7311145

MHRA-UKPAR – Extra power Pain Reliever Caplets/Tablets
PL 16028/0147-8
Tesco 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 read the leaflet, carefully, to 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 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 reliever from paracetamol (analgesic) you may start. This tablets are for the relief of mild to moderate pain.

These tablets are also suitable for use by elderly people, patients with renal and liver problems, and those who are pregnant or breastfeeding.

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.
• are under 16 years old.
• are pregnant or breastfeeding.

3. How to take this medicine
Swallow the tablets 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 6 tablets in any 24 hour period. Do not take more than 8 tablets in any 48 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. This medicine 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.

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 which worries you, stop taking the medicine immediately, and see your doctor or pharmacist:

Rare side effects are:
• allergic type reactions such as rash, urticaria, swelling, and tightness of the chest, wheeze or cough, breathlessness or difficulty breathing.
• bleeding in the stomach or bowel lining, which may cause haematemesis, melaena, which should stop before you take this medicine. Also, if you have a history of ulcers or bleeding disorder.
• any other bleeding disorder.

5. How to store your medicine
Keep all medicines out of the reach and sight of children. Do not take 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 300 mg
• caffeine 40 mg.

The other ingredients are:
• maize starch, colloidal silicon dioxide, hydroxypropyl methylcellulose, methacrylate copolymer, mannitol, magnesium stearate, hypromellose, colloidal silicon dioxide, iron oxide yellow.

This product is available in a pack of 16 tablets.

7. Who makes this medicine?
The Marketing Authority holder is Teapak Healthcare Ltd, Ockford, South Yorkshire, S73 8P. The manufacturer is Waddington Laboratories Ltd, Stourton, Devon, EX10 9LG, UK.

Please read this leaflet again.

MHRA-UKPAR – Extra Power Pain Reliever Caplets/Tablets

PL 16028/0147-8

- 36 -
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 are advised to use it only if your condition is likely to persist, or if symptoms do not improve. If you feel it is necessary to use it regularly, please ask your pharmacist prior to administration of this medicine.

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 inflammation.
- 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, period pain, toothache, minor aches, back pain, minor aches and pains, joint aching and stiffness, flu-like symptoms and fever in children.

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 haemorrhoids 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 are on any of the following medicines or if you are trying to conceive:
- aspirin or other anti-inflammatory agents which can make it difficult to clot blood such as ibuprofen.
- medicines to control bleeding such as warfarin or any other anti-platelet agents which can make it difficult to clot blood such as ibuprofen.
- medicines called anti-coagulants, which are used to thin the blood such as warfarin and other anti-platelet agents which can make it difficult to clot blood such as ibuprofen.
- medicines to control bleeding such as warfarin or any other anti-platelet agents which can make it difficult to clot blood such as ibuprofen.
- medicines to control bleeding such as warfarin or any other anti-platelet agents which can make it difficult to clot blood such as ibuprofen.
- medicines to control bleeding such as warfarin or any other anti-platelet agents which can make it difficult to clot blood such as ibuprofen.

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

Adults, the elderly and young persons over 16 years old or 5 years and adults over 16 years old. Do not take more than 1 tablet in any 24 hour period. Do not take more than 4 tablets in 4 hours. Do not take more than 8 tablets in 24 hours.

Do not give to children under 16 years.

There is a possible association between aspirin and Reye's syndrome when given to children.

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 unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist:

- Rare side effects:
  - allergic reactions such as rash, itching, redness or swelling of the face, mouth or throat.
  - stomach pain or indigestion.
  - feeling tired or weak.
  - feeling dizzy, light-headed or faint.
  - feeling dizzy, light-headed or faint.

- Common side effects:
  - headache.
  - feeling sick or vomiting.
  - feeling hot or cold.
  - feeling tired, weak or dizzy.
  - feeling drowsy.

- Rare side effects:
  - allergic reactions such as rash, itching, redness or swelling of the face, mouth or throat.
  - stomach pain or indigestion.
  - feeling tired or weak.
  - feeling dizzy, light-headed or faint.
  - feeling dizzy, light-headed or faint.

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 the active ingredients:
- paracetamol 200mg, aspirin 300mg, caffeine 45mg.
- Other ingredients: microcrystalline cellulose, cornstarch, talc, lactose, polyethylene glycol, talc, magnesium stearate.

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

7. Who makes this medicine?
The Marketing Authorisation holder is Wilko Healthcare Ltd., Dodworth, South Yorkshire S75 9SR. The manufacturer is Witten Laboratories Ltd., Buriton, Fareham, PO16 8JL, UK.

Text revised: January 2009.
PL 19/02/14
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.
Lloyd's Pharmacy Extra Power Pain Reliever Caplets/Pain Reliever Tablets
Paracetamol, aspirin and caffeine
10 Tablets

Morrison's Extra Power Pain Reliever Caplets/Pain Reliever Tablets
Paracetamol, aspirin and caffeine
10 Tablets

MHRA-UKPAR –Extra power Pain Reliever Caplets/Tablets
PL 16028/0147-8