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Summary of Product Characteristics Page 13
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Labelling .............................. Page 38
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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Pharmaceutical assessment Page 5
Preclinical assessment Page 8
Clinical assessment Page 9
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 AUTHORIZATI ON 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.
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 FOR ASSESMENT**

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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 10th February 2009.</td>
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<tr>
<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 7th May 2009.</td>
</tr>
<tr>
<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 21st July 2009.</td>
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<td>The application was determined on 23rd September 2009.</td>
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**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
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Wilko Extra Power Pain Reliever Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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<tr>
<td>Paracetamol</td>
<td>200</td>
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<td>Caffeine</td>
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</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.

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/PTR, 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

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3 PHARMACEUTICAL FORM
Tablet

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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.

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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:-

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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/PTR, 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 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 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 AUTHORITY
Galpharm Healthcare Ltd
Upper Cliffe Road
Dodworth Business Park
Dodworth
South Yorkshire
S75 3SP
United Kingdom

8 MARKETING AUTHORIZATION NUMBER(S)
PL 16028/0148

9 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION
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.
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 this product 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 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 headaches, rigours, toothache, back pain, chest pain and period pain. They may be taken for symptomatic relief of migraine, neuralgia pain, vertigo, menorrhagia, bladder, muscular aches and pains, joint swelling and stiffness, PMS, tiredness and labour pains.

2. Is this medicine suitable for you?

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

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

Immediate medical advice should be sought in an 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 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, or anything else that makes you feel uncomfortable, stop taking the medicine immediately, and see your doctor or pharmacist.

- Pillage, nausea or vomiting
- Stomach pain or indigestion
- Headache or dizziness
- Skin rash or nettle rash

Rare side effects are:
- allergic-type reactions such as skin rash, cough, swelling and tightness of the chest, fever or chills, brought on by aspirin
- bleeding in the ears, nose, mouth, which may look like coffee ground stools when you are being sick. 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 excessive bleeding.

Do not use the medicine if you are allergic to aspirin or any of the other ingredients in this medicine.

5. How to store this medicine

- Keep in a dry place, below 25¡C.
- Do not use after the expiry date printed on the pack.
- Keep out of children’s reach.

6. What is in this medicine?

Each tablet contains the active ingredients paracetamol 325mg, aspirin 325mg and caffeine 45mg. Other ingredients are microcrystalline cellulose, hypromellose, white, lactose, sodium lauryl sulphate, magnesium stearate and talc.

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

7. Who makes this medicine?

The Marketing Authorisation holder is GlaxoSmithKline Consumer Healthcare Ltd, Dagenham, Southend, Essex, SS16 0TR, United Kingdom.

MHRA-UKPAR –Extra power Pain Reliever Caplets/Tablets
PL 16028/0147-8 - 28 -
Galpham Extra Power Pain Reliever Caplets
Penicillamine, 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 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:
• penicillamine 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 ingredients help to relieve mild to moderate pain in conditions such as:
• rheumatoid arthritis
• osteoarthritis
• gout
• period pain
• migraine
• headache
• earache

You should take this caplet if you:
• have mild to moderate pain
• have conditions that aspirin and caffeine usually help with
• have conditions that paracetamol usually helps with

2. Is this medicine suitable for you?

Do not take this caplet 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 are taking blood clotting disorder drugs
• are pregnant or breast feeding
• are under 16 years old

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

Information about some of the ingredients in this medicine:

Contains aspirin (ASA). If you have been told by your doctor that you have an allergy to aspirin or to some sugars, contact your doctor before taking this medicine.

3. How to take this medicine

Read the tablets with water. Do not chew.

Adults, the elderly and young persons over 65 years: 1 or 2 tablets every 4 hours as required. Do not exceed more than 5 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. Children are at risk of Reye’s syndrome, 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, so 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 that happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rarer side effects are:
• allergic reactions such as skin rash, swelling of the face, ears, mouth or eyes, breathing difficulties, breathlessness, tightness of the chest
• shivering, feeling faint, fits
• attacks of severe pain in the muscles
• symptoms of acute liver failure
• symptoms of blood disorders
• bleeding problems

5. What is this medicine?

Each tablet contains the active ingredients:
• penicillamine 125 mg
• aspirin 325 mg
• caffeine 120 mg

The other ingredients are: sodium starch glycolate, povidone, magnesium stearate, talc, starch, and colouring (E129).

This medicine is available as a pinkish-white tablet.

6. Who makes this medicine?

The Medicine and Healthcare products Regulatory Agency (MHRA) is the body responsible for regulating medicines and healthcare products in the United Kingdom. It is independent of the Department of Health and other government departments.

MHRA-UKPAR –Extra power Pain Reliever Caplets/Tablets
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Lloyds Pharmacy Extra Power Pain Reliever Caplets/Tablets

Ingredients: 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 sensibly. If you have any doubts, you should consult your doctor or pharmacist.

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

This medicine contains:
- paracetamol which is a pain reliever, anti-inflammatory, and reduces your body temperature when you have a fever.
- aspirin which is a pain reliever, anti-inflammatory, and helps to reduce swelling.
- caffeine which is a stimulant that increases the alertness from paracetamol and makes you more alert.

These ingredients help to relieve moderate pain, headache, muscular aches, menstrual pain, cold symptoms, and upper respiratory tract infections. They are also helpful for the management of such conditions as rheumatoid arthritis, enteritis, and influenza. These side effects are rare to serious but may include:
- nausea and vomiting
- constipation
- diarrhea
- dizziness
- headache

2. Is this medicine suitable for you?

No, or if it is not:
- allergic to paracetamol, aspirin, caffeine or any of the other ingredients
- have, or have had, a particular problem
- have a liver or kidney disorder
- are pregnant or breastfeeding
- are under 16 years old

- are taking medicines, sold in pharmacies, to stop your symptoms.

3. How to take this medicine

Swallow the tablets whole with water. Do not chew.

Children: the elderly are young persons over 16 years. 1 or 2 tablets every 4 hours as required. Do not take more than 4 tablets in any one day. Do not take more than 8 tablets in a 24 hour period.

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:
  - severe skin reactions such as skin rash, swelling, and tightness of the chest
  - allergic to aspirin, milk, eggs, or nuts
  - feeling困倦 or feeling tired

5. How to store your medicines

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 this medicine?

Each tablet contains the active ingredients:
- paracetamol 200 mg, aspirin 300 mg, and caffeine 40 mg. The tablets are made in a tablet form, with cornstarch, sodium bicarbonate, sodium citrate, lactose, magnesium stearate, talc, and the inactive ingredient - cornstarch.

This product is available in a pack of 16 tablets.

7. How do I take it?

Take 1 Tablet every 4 hours as required. Do not take more than 8 tablets in a 24 hour period.

8. What should I do if I take too much?

Contact your doctor or local hospital.

9. Who makes this medicine?

This medicine is manufactured by Cepham Healthcare Ltd, Downderry, South Hooe, Plymouth PL7 5PA. The manufacturer is also available at: GSK Healthcare Ltd, Bracknell, Berkshire, RG12 8YX, UK. Text Reynolds on 0208/0217-8-

MHRA-UKPAR –Extra power Pain Reliever Caplets/Tablets

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Morrison’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 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 fever

These tablets are for the relief of mild to moderate pain including headache, migraine, toothache, minor burns and scalds, minor cuts and abrasions, period pain, menstrual pain, indigestion, heartburn, diarrhoea, nausea and vomiting, and kidney and urinary tract infections.

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.
- suffer from any liver problems, including alcoholic liver disease
- have asthmatic
- have any intolerance to simple ingredients.

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 high blood pressure such as angiotensin-converting enzyme inhibitors
- medicines to control high blood pressure such as angiotensin receptor blockers
- medicines to treat high blood pressure such as calcium channel blockers
- medicines to treat high blood pressure such as diuretics

If you are taking any other medicines, please check with your doctor or pharmacist before stopping this medicine.

3. How to take this medicine
Take the tablets with or without food. Do not chew.

Adults and children over 12 years of age: 1 tablet every 4–6 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 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.

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:
- allergic type reactions such as rash, fever, sore throat, difficulty breathing, swelling of the face, mouth, tongue or throat
- dark urine
- bloody or frothy vomit
- difficulty in breathing
- fitting or loss of consciousness
- convulsions
- fast heart rate
- difficulty in talking
- swelling of the limbs
- blood in the urine
- blood in the stools
- breathlessness
- swelling of the face
- sudden weight gain

5. How to store your medicine
Keep the medicine 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 300 mg
- caffeine 45 mg
- Other ingredients: microcrystalline cellulose, colloidal silicon dioxide, sodium citrate, croscarmellose sodium, hypromellose, talc, magnesium stearate.

This product is available in a pack of 16 tablets.

7. Who makes this medicine?
The Marketing Authorisation Holder is Gapharm Healthcare Ltd, Coddenham, South Walsham IP25 7BP. The manufacturer is Waterstone Laboratories Ltd, Braintree, Essex, CM77 7DL. UK.

Text Revised: 01-11-09

MHRA-UKPAR –Extra power Pain Reliever Caplets/Tablets PL 16028/0147-8
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Numark Extra Power Pain Reliever Tablets
Paracetamol, Aspirin, Caffeine
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 if you have a fever
- aspirin which is a pain reliever and helps reduce bleeding
- caffeine which helps to increase the pain relief from paracetamol and makes you more alert.

These tablets are for the relief of moderate pain including headache, migraine, toothache, minor pain, sore throat and period pain. They are also for symptomatic relief of cold, flu, aches and pains, joint aches and stiffness, toothache and headache.

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
- you have had any other blood clotting disorders
- you are pregnant or breast feeding
- you are under 16 years old

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 10 tablets in any 24-hour period. Do not take more than 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.

4. Possible side effects
Most common side effects:
- feeling nervous, sweating, dizziness, nausea, vomiting, diarrhea, stomach pain, headache, rash
- feeling drowsy, feeling light-headed, ringing in the ears, changes in hearing, eye pain, sensitivity to light
- feeling sleepy or tired
- dry mouth

If you experience any of these side effects, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
- allergic reactions such as rash, itch, skin swelling, breathing difficulty, swelling of the face, tongue or throat
- yellowing of the skin or eyes
- jaundice
- unusual bleeding or bruising

If any of these side effects occur, stop taking the medicine and see your doctor or pharmacist immediately.

5. How to store your medicine
Keep in a cool, dry place. Do not store above 25°C. Do not freeze. Keep out of the reach and sight of children.

6. What is in this medicine?
Each tablet contains the active ingredients:
- paracetamol 250 mg
- aspirin 360 mg
- caffeine 95 mg

Other ingredients are:
- polvobutylmethacrylate, sodium carboxymethylcellulose, colloidal silicon dioxide, magnesium stearate, polyethylene glycol and hydrogenated vegetable oils.

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

7. Who makes this medicine?
 unquestioned.
Read all of this leaflet carefully before you take this medicine because it contains important information about its use.

This medicine is available without prescription, however, you still need to use this product carefully to get the best results. If you continue to use this leaflet, you can find more information about its use.

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

This medicine contains:
- paracetamol, which is a pain reliever and fever reducer.
- aspirin, which is also a pain reliever and fever reducer.
- caffeine, which increases the effect of the other ingredients.

These ingredients are for the relief of mild to moderate pain and fever and to reduce the pain relief from paracetamol and aspirin. This medicine is not suitable for children under 16 years old.

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.
- you have hemophilia or any other blood clotting disorder.
- you are pregnant or breast feeding.
- you are under 16 years old.

- you 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 alcoholic 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 feeling sick or feeling sick such as metoclopramide or domperidone.
- medicines called anti-epileptics, which are used to slow the blood such as warfarin and other blood thinners - you may need a dose reduction of paracetamol but should consult your doctor if you start taking a new medicine as a result.
- other anti-inflammatory medicines such as ketorolac and paracetamol.
- antibiotics, used as a stomach treatment, such as levofloxacin or antibiotics, such as cefuroxime or amoxicillin.
- medicines used to control seizures in epilepsy such as phenobarbital or sodium valproate.
- antidepressants, used in cancer therapy or to treat patients with bipolar disorder.
- methylphenidate, used for ADHD and ADHD and bipolar disorder.
- tablets, used in cancer therapy or for depression.
- paracetamol and aspirin.

Please turn over.

3. How to take this medicine

Swallow the tablets whole with water or dry.

Adults, the elderly, and young persons over 16 years: take 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 4 tablets every 4 hours. Do not give to children under 16 years.

There is a possible association between aspirin and Reye's Syndrome if given to children. Reye's Syndrome is a very rare disease, which can be fatal. For this reason aspirin should be given to children under 16 years, unless in 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 if you experience any of the following side effects, or if 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.
- a feeling of a heavy head.
- breathing difficulties, which can be life-threatening.

If you have these, seek advice from your doctor or pharmacist. If you experience any of these, seek advice from your doctor or pharmacist.

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 300 mg.
- aspirin 360 mg.
- caffeine 65 mg.
- paracetamol 66 mg.
- aspirin 4 mg.
- caffeine 4 mg.

The other ingredients are:
- starch, holding of the medicines such as tartaric acid, citric acid, polysorbate 60 and polysorbate 80.

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

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, sore throat, tooth pain and period pain. They are also helpful in the relief of sprains, strains, muscular aches and pains, joint swelling and stiffness, cold, rheumatic and arthritic pain.

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 disorders
- are pregnant or breast-feeding
- are under 16 years old
- are taking medicines called anticoagulants, 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 abuse
- 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 fats in the blood such as statins
- medicines to control high blood pressure or diabetes
- medicines called anticoagulants, which are used to thin the blood such as warfarin and other oral anticoagulants, you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- other anti-platelet medicines such as aspirin
- medicines, used as a stomach treatment, such as antacids and antiflatulents, such as domperidone and omeprazole
- medicines used to control vomiting in infants and children, such as promethazine, albuterol, and promethazine hydrochloride
- contains paracetamol and aspirin. Do not take with any other paracetamol-containing products.

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

Information about some or the ingredients in this medicine:
- Colestyramine (CB435). 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
Swallow the tablet whole with water. Do not chew.

Adults, the elderly and young persons over 16 years:
1 tablet 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 10 tablets every 48 hours.

Do not give to children under 16 years of age. There is a possible association between aspirin and Reyes’ Syndrome when given to children. Reyes 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 this medicine with this leaflet.

4. Possible side effects
Most people do not have any side effects while taking this medicine. However, I may experience any of the following side effects, or another serious side effect, 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 swelling of the lips and throat
- bleeding in the stomach or bowel lining, which can cause black stools, dark patches on the skin, a rash or bleeding from the nose or mouth
- jaundice, yellow coloration of the skin, urine or eyes
- blood in the urine
- blood in the stool
- convulsions, loss of consciousness, collapse
- increased irregular or fast heart rate
- dizziness
- trembling
- or convulsions, used to treat heart disease and strokes
- medicines to treat high blood pressure which can cause dizziness, fatigue, muscle cramps, drowsiness, depression, dry mouth, difficulty concentrating, nervousness, headache, nausea, heartburn or constipation
- medicines to treat high blood pressure which can cause dizziness, fatigue, muscle cramps, drowsiness, depression, dry mouth, difficulty concentrating, nervousness, headache, nausea, heartburn or constipation
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- medicines to treat high blood pressure which can cause dizziness, fatigue, muscle cramps, drowsiness, depression, dry mouth, difficulty concentrating, nervousness, head
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 relieving effect of paracetamol and makes you more alert.

These tablets are for the relief of mild to moderate pain including headache, migraine, backache, new pain, pain in the arm and leg, pain in the hand and foot, muscle and joint pain, toothache and stiffness, etc.

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 had a severe reaction to this medicine or any other medicine containing paracetamol or aspirin
- 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 liver or kidney problems, including diabetes or liver disease
- have arthritis
- 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 and heart conditions
- medicines to treat blood clots or giving blood.
- medicines to control bleeding, such as heparin or subcutaneous heparin
- medicines used to control bleeding, such as heparin or subcutaneous heparin
- medicines used to control blood pressure, such as losartan or furosemide
- medicines used to control blood pressure, such as losartan or furosemide
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- medicines used to control blood pressure, such as losartan or furosemide
- medicines used to control blood pressure, such as losartan or furosemide

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 4 tablets every 4 hours.

Do not give to children under 16 years.

If you are pregnant or breast feeding, ask your doctor or pharmacist before taking this medicine.

4. Possible side effects

Most people do not have any side effects from 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, lips, tongue, or throat
- stomach pain, bloating, feeling sick, or diarrhoea
- bleeding in the stomach or bowel (may be bright red)
- blood in the urine
- trouble with breathing
- blood in the vomit
- swallowing difficulties
- severe skin reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis (also known as Lyell's syndrome)
- high fever or shivering
- unusual sensitivity to light or skin blisters
- muscle weakness
- vision or hearing changes
- severe headache
- sudden weight gain
- sudden increase in the size of a breast

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 325 mg, aspirin 325 mg and caffeine 45 mg. The other ingredients are: starch, magnesium stearate, colloidal silicon dioxide (E551), sodium lauryl sulphate, hydroxypropyl cellulose, magnesium stearate, hypromellose, polyethylene glycol and polysorbate 80.

This product is available in pack sizes of 10 tablets.

7. Who makes this medicine?

The Marketing Authorisation Holder is GlaxoSmithKline Healthcare Limited, Cleveland, Crowthorne, Berkshire RG11 2LX, U.K.

Tad Framford January 2003.

PL 1062/0/447-1
Tesco Extra Power Pain Reliever Caplets
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.

This medicine is available without prescription; however, you should read this leaflet 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 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;
- codeine which helps to increase the pain relief from paracetamol; instructions for use start here.

These tablets are for the relief of short-term, moderate pain due to headache, toothache, cold symptoms, minor dental, periodontal, muscle, and joint pain, backache, and stiffness in joints and muscle. This medicine is not suitable for children under 16 years of age.

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;
- are breast feeding;
- are under 16 years of age;
- are pregnant or breast feeding.

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 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, and this 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 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 this medicine and the 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, stop taking the medicine immediately, and see your doctor or pharmacist:
- are taking medications called anticoagulants, to stop your blood from clotting;
- have a history of minor bleeding problems, including alcohol abuse.

If you are taking any of the following medicines please see your doctor before taking this medicine:
- other pain relievers, for example, those containing codeine or paracetamol;
- anti-inflammatory drugs for pain and swelling;
- medicines to control pain and fever, for example, those containing aspirin and paracetamol;
- medicines to control pain and fever, for example, those containing aspirin and paracetamol;
- medicines to control pain and fever, for example, those containing aspirin and paracetamol;
- medicines to control pain and fever, for example, those containing aspirin and paracetamol.

5. How to store your medicine
Keep all medicines out of the reach of children and away from sources of heat and heat or direct sunlight.

6. What is in this medicine?
Each tablet contains the active ingredients:
- paracetamol 325 mg, aspirin 300 mg, and caffeine 400 mg. The other ingredients are:
- sodium lauryl sulphate, hydroxypropyl methylcellulose, hypromellose, magnesium stearate, talc, glycerol, water, sodium lauryl sulphate, hydroxypropyl methylcellulose, hypromellose, magnesium stearate, talc, glycerol, water.

This product is available in a pack of 16 tablets.

7. Who makes this medicine
The Marketing Authorisation holder is Gabagh Healthcare Ltd, Dodderhill, South Yorkshire S75 3EF. The manufacturer is Waston Laboratories Ltd, Thornton, Devon, EX19 5LQ, UK.

(Revised: January 2009)
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, if you are unsure whether this product is right for you, please keep this leaflet as you may need to read it again. Ask your pharmacist for more information on 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, period pain, toothache, colds, cough, sore throat and period pain. They are also useful for aches and pains, backache, muscle aches and pains, joint swelling and stiffness, flu-feverishness 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 anticoagulants, to stop your blood from clotting.
- have an intolerance to aspirin.

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 colestipol.
- medicines to control blood clotting or stenting such as warfarin or clopidogrel.
- medicines called anti-coagulants, which are used to thin the blood such as warfarin and other aspirins.
- warfarin or clopidogrel. Take special care when you take aspirin or other anti-coagulant medicines such as heparin and warfarin.

- do not take with alcohol.

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 intolerance to certain sugars, contact your doctor before using this medicine 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 4 tablets in any 24 hour period. Do not take more than 4 times a day.

Do not give to children under 16 years.

There is a possible interaction between aspirin and your medicines, please consult your doctor. People with diabetes, liver disease, kidney disease, or those on certain medicines should consult their doctor.

Do not exceed the stated dose.

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

Before taking any new medicine, you must see a doctor or pharmacist.

Avoid alcohol and other medicines. If you experience any side effects or unusual effects, stop taking the medicine immediately, and see your doctor or pharmacist.

4. Possible side effects

Most people do not experience 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 itchy rash, wheezing and tightness of the chest
- diarrhea or constipation, brought on by aspirin
- bleeding from the nose or gums, which can be serious in the elderly, a sign of bleeding to the blood in someone who may have a bleeding disorder. These side effects may be caused by the use of aspirin or other anti-thrombotic medicine that changes the way the blood clots or a blood disorder.

Your doctor may give you a different medicine and advise you to take aspirin or other anti-thrombotic medicine that changes the way the blood clots.

The amount of ingredient in this medicine is listed below:

- Paracetamol: 1 g
- Aspirin: 250 mg
- Caffeine: 50 mg

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

7. Who makes this medicine?

The Marketing Authorisation Holder is Cephalon Healthcare Ltd, Doodsbury, South Yorkshire S75 1SH. The manufacturer is Critical Laboratories Ltd, Birchen Grove, EC3 8DL, UK. 

Tel: 01622 521478. Fax: 01622 522282. 

PL 10269/0147-8

MHRA-UKPAR – Extra power Pain Reliever Caplets/Tablets

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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.