1 NAME OF THE MEDICINAL PRODUCT

Flu Relief Capsules with Decongestant

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol EP 500.0mg
Phenylephrine Hydrochloride EP 12.18mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of symptoms of colds and influenza, including aches and pains, headache, nasal congestion sinus pain and feverishness.

4.2. Posology and Method of Administration

For oral administration.

Adults and children over 12 years of age: 1 capsule to be taken every 4 hours. Maximum of 4 capsules in any 24 hours.

Children under 12 years: Not recommended.

4.3. Contra-indications

Patients with known hypersensitivity to Paracetamol or Phenylephrine or any of the other ingredients. Also contra-indicated during pregnancy and in those taking monoamine oxidase inhibitors or tricyclic anti-depressant drugs.

4.4. Special Warnings and Precautions for Use

Paracetamol should be used with care in patients with severe renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

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.
Do not to take with any other paracetamol-containing products.

Phenylephrine should be used with care in patients with hyperthyroidism, cardiovascular disease, diabetes mellitus, closed angle glaucoma, prostatic enlargement and hypertension.

Do not exceed the stated dose.
If symptoms persist consult your doctor.
Keep out of the reach of children.

4.5. Interactions with other Medicaments and other forms of Interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone; and absorption reduced by cholestyramine. The anti-coagulant 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.

With phenylephrine there is a possibility that an increased risk of' arrhythmias may occur in patients receiving cardiac glycosides or tri-cyclic anti-depressants. Phenylephrine interacts with monoamine oxidase inhibitors; it should not therefore, be taken by patients receiving monoamine oxidase inhibitors or within 14 days of stopping such medication.

4.6 Pregnancy and lactation

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 contra-indicate breast feeding.

Phenylephrine should not be taken during pregnancy as it has been reported to cause fetal hypoxia. Excretion in breast milk is reported to be minimal.

4.7. Effects on Ability to Drive and Use Machines

None.

4.8. Undesirable Effects

Undesirable effects with paracetamol are rare, however, hypersensitivity including skin rashes may occur. There have been a few reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

Phenylephrine can cause the adverse effects typical of sympathomimetics including, dizziness, hypertension and tachycardia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

Paracetamol
Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g of 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 depleted, e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms
Symptoms of paracetamol overdose 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 24 hours from ingestion should be discussed with the NPIS or a liver unit.

Phenylephrine hydrochloride
Features of severe overdose of phenylephrine include haemodynamic changes and cardiovascular collapse with respiratory depression. Treatment includes early gastric lavage and symptomatic and supportive measures. Hypertensive effects may be treated with an i.v. alpha-receptor blocking agent.

Phenylephrine overdose is likely to result in: nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), dysuria, urinary retention (most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy).

Additional symptoms may include hypertension, and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However the amount required to produce serious phenylephrine toxicity would be greater than that required to cause paracetamol-related liver toxicity.

Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking medicinal products such as phentolamine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic actions probably due to the inhibition of prostaglandin biosynthesis.

Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effect on adrenergic receptors. It has predominantly alpha-adrenergic activity and is without significant stimulating effects on the central nervous system at usual doses. It may be given orally to relieve nasal congestion.

5.2. Pharmacokinetic Properties

Paracetamol is readily absorbed from the gastro-intestinal tract and peak plasma concentrations usually occur 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and largely excreted in the urine as sulphate and glucuronide conjugates. Less than 5% is excreted unchanged. The elimination half-life varies from about 1 to 4 hours.

Phenylephrine is readily absorbed after oral administration but is subject to extensive presystemic metabolism. Peak plasma concentrations are achieved in 1 to 2 hours. Phenylephrine is biotransformed in the liver and is excreted along with its metabolites in the urine, with less than 20% as unchanged drug.

5.3. Preclinical Safety Data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Colloidal Anhydrous Silica BP, Sodium Starch Glycollate BP, Magnesium Stearate BP. The capsule shell contains: Gelatin EP, Titanium Dioxide EP (E171), Patent Blue V (E131), Yellow Iron Oxide (E172).

6.2. Incompatibilities

None.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store below 25°C in a dry place.

6 PHARMACEUTICAL PARTICULARS

6.5 Nature and contents of container

Blister strips comprised of 30 micron hard temper Aluminium lidding foil with 250 – 300 micron PVC base material. or Blister strips comprised of 30 micron hard temper Aluminium lidding foil with 250 micron PVC/PVdC (40- 90 gsm) base material. or Blister strips comprised of 20 micron Aluminium /15micron PVC lidding foil with 250300 micron PVC base material. or Blister strips comprised of 20 micron Aluminium/ 15micron PVC lidding foil with 250 micron PVC/PVdC (40 – 90gsm) base material. or Blister strips comprised of 35-41gsm Glassine paper/9micron Aluminium lidding foil with 250 – 300micron PVC base material. or Blister strips comprised of 35-41gsm Glassine paper/9micron Aluminium lidding foil with 250micron PVC/PVdC (40-90gsm) base material.

Blister pack sizes of 8, 10, 12 or 16 capsules.

6.6. Instruction for use and handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Galpharm Healthcare Limited
Wrafton
Braunton
Devon
EX33 2DL
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 16028/0031

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11 September 1997

10 DATE OF REVISION OF THE TEXT

28/07/2016