SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINALPRODUCT

Panda night caplets

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each film-coated caplet of contains 500 mg of paracetamol and 25 mg of diphenhydramine HCL.

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

A light blue oval shaped film coated caplets with PANDA inscribed

on one side and a mark line on the other side.

4. Clinical particulars

4.1 Therapeutic indications

Panda Night is indicated in relief of pain associated with sleep disturbances. It is used for the short term treatment of bedtime pain, for example rheumatic and muscle pain, backache, neuralgia, toothache, migraine, headache and menstrual pain.

4.2 Posology and method of administration

Adults and Children Over 12 years.

1-2 caplets to be taken at bedtime.

Not to be taken for more than 7 consecutive nights without consulting a doctor.

Children Below 12 Years

Panda Night is not recommended for children unless under strict medical supervision

Method of administration

Panda Night caplets should be swallowed without crushing and with sufficient amount of liquid.

4.3 Contraindications

Hypersensitivity to paracetamol, diphenhydramine hydrochloride or other constituents.

Porphyria.

4.4 Special warnings and precautions for use

Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.

The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Use with caution in patients with glutathione depletion due to metabolic deficiencies.

Avoid use of other antihistamine-containing preparations, including topical antihistamine and cough and cold medicines.

Avoid concurrent use with alcohol, as diphenhydramine may increase the sedative effects of alcohol. Therefore, alcohol should be avoided (see Interactions).

Use with caution in patients with epilepsy or seizure disorders, myasthenia gravis, narrow-angle glaucoma, prostatic hypertrophy, urinary retention, asthma, bronchitis and chronic obstructive pulmonary disease (COPD), hepatic impairment and mild to moderate renal impairment.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol

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

Diphenhydramine

Diphenhydramine hydrochloride may potentiate the sedative action of alcohol and other central nervous system depressants (e.g. codeine, tranquilizers, hypnotics and anxiolytics) and other antihistamines.

Monoamine Oxidase inhibitors (MAOIs) may prolong and intensify the antimuscarinic effects of diphenhydramine. The product should be used with caution with MAOIs or within 2 weeks of stopping an MAOI.

As diphenhydramine has anticholinergic activity the effects of some anticholinergic drugs (e.g. atropine and tricyclic antidepressants) may be potentiated. This may result in tachycardia, dry mouth, blurred vision, gastrointestinal disturbances, urinary retention and headache.

Diphenhydramine is an inhibitor of the cytochrome p450 isoenzyme CYP2D6. Therefore, there may be a potential for interaction with drugs that are primarily metabolized by CYP2D6, such as metoprolol and venlafaxine.

4.6 Pregnancy and Lactation

This product should not be used during pregnancy unless the expected benefit justifies the potential risk to the foetus. The lowest effective dose and shortest duration of treatment should be considered.

Paracetamol

As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, the lowest effective dose and shortest duration of treatment should be considered.

Diphenhydramine

There are no adequate data from the use of diphenhydramine in pregnant women. Animal studies are insufficient with respects to pregnancy. The potential risk for humans is unknown. Use of sedating antihistamines during the third trimester may result in reactions in the newborn or premature neonates.

Lactation

This product should not be used whilst breast feeding without medical advice.

Human studies with paracetamol have not identified any risk to lactation or the breast-fed offspring. Paracetamol crosses the placental barrier and is excreted in breast milk.

Diphenhydramine has been detected in breast milk, but the effects of this on breast-fed infants are unknown.

4.7 Effects on ability to drive and use machines

May cause drowsiness, dizziness, blurred vision, cognitive and psychomotor impairment, which can seriously affect patients' ability to drive and use machinery. If affected they should not drive or operate machinery.

4.8 Undesirable effects

Sedation, drowsiness, disturbance in attention, unsteadiness, dizziness

Fatigue,dry mouth,thrombocytopenia ,agranulocytosis .

4.9 Overdose

Paracetamol

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

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 and liver injuries peak after 4-6 days. 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.

Diphenhydramine

Diphenhydramine overdose is likely to result in effects in effects similar to those listed under adverse reactions. Additional symptoms may include mydriasis, fever, flushing, agitation, tremor, dystonic reactions, hallucinations and ECG changes including QT prolongation. Large overdose may cause rhabdomyolysis, convulsions, delirium, toxic psychosis, arrhythmias, coma and cardiovascular collapse

Treatment should be supportive and directed towards specific symptoms. Convulsions and marked CNS stimulation should be treated with parenteral diazepam. Further management should be as clinically indicated or as recommended by the national poisons centres where applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Paracetamol has analgesic and antipyretic effects. It is only a weak inhibitor of prostaglandin biosynthesis, although there is some evidence to suggest that it may be more effective against enzymes in the CNS than those in the periphery. This fact may partly account for its ability to reduce fever (a central action) and to induce analgesia.

Diphenhydramine is an ethanolamine class antihistamine that acts predominantly as a competitive but reversible inhibitor of histamine at the H_1 receptor sites. However, like most H_1 antihistamines it has additional sedative anticholinergic (antimuscarinic) and local anaesthetic properties.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Concentration in plasma generally reaches a peak in

30-120 minutes; plasma half-life is 1-4 hours. Paracetamol is relatively uniformly distributed throughout most body fluids. Plasma binding is variable. Excretion is almost exclusively renal in the form of conjugates. Diphenhydramine is well absorbed from the gastrointestinal tract following oral administration. Peak plasma concentrations are achieved in 2 to 3 hours and the effects usually last 4 to 6 hours. Diphenhydramine is extensively metabolised mainly in the liver, and excreted usually as metabolites in the urine.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

Povidone PVP K-30
Croscarmellose sodium
Microcrystalline cellulose 101
Isopropyl alcohol
Prosolve 90
Talc
Magnesium stearate
Sepifilm 003 (HPMC)
Titanium dioxide
FD&C Blue

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C in a dry place.

6.5 Nature and contents of container

The primary packaging materials used is: Transparent colorless PVC/PVDC/Aluminum blister

One Aluminum / PVC blisters contain 10 x 10 caplets packed in a printed cardboard case.

One Aluminum / PVC blisters contain 2 x 10 caplets packed in a printed cardboard case.

6.6 Special precautions for disposal

No special requirements

7. APPLICANT/MANUFACTURER

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