

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 1000mg, phenylephrine hydrochloride 12.2mg, Powder for oral solution, Blackcurrant flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One sachet contains:

1000mg Paracetamol

12.2mg Phenylephrine hydrochloride (equivalent to 10mg phenylephrine base)

Excipients

Sucrose 2351mg

Aspartame 53mg

Carmoisine 4.9mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution, sachet

Purple powder

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For relief of symptoms of colds and influenza, including the relief of headaches, aches and pains, sore throat, nasal congestion and lowering of temperature.

4.2 Posology and method of administration

Dissolve the contents of one sachet in a standard mug of hot, but not boiling, water (approx. 250ml). Allow to cool to a drinkable temperature.

Adults: One sachet

May be repeated every 4-6 hours as required

Adolescents over 15 years of age: One sachet

May be repeated every 6 hours as required

Maximum of 4 doses (4 sachets) in 24 hours

Not recommended for children under 15 years, except on medical advice.

Elderly: No special dosage modifications are required.

4.3 Contraindications

Hypersensitivity to paracetamol, phenylephrine or any of the excipients

Severe ischaemic heart disease

Severe hepatic impairment

Moderate to severe renal impairment

Hypertension

Severe hyperthyroidism

Narrow-angle glaucoma

Use in patients who are currently taking or have taken monoamine oxidase inhibitors (MAOIs) within the last two weeks

Use in patients with urinary retention

Use in patients who are currently taking other sympathomimetic drugs

4.4 Special warnings and precautions for use

Paracetamol should be administered only with particular caution in patients with impaired hepatic function, including acute hepatitis, alcoholism, haemolytic anaemia or patients taking hepatotoxic medicinal products. Use of paracetamol in patients with impaired hepatic function and in patients receiving long-term therapy with high doses of paracetamol requires the regular monitoring of hepatic function.

Paracetamol should be administered with particular caution in patients with chronic malnutrition (low reserves of hepatic glutathione) or glucose-6-phosphate dehydrogenase deficiency.

Use with caution in patients with hyperthyroidism

Use with caution in patients receiving digitalis, beta-adrenergic blockers, methyldopa or other anti-hypertensive agents.

Use with caution in patients with prostatic hypertrophy as they may be susceptible to urinary retention.

Use with caution in patients with Raynaud's Phenomenon or diabetes.

Sympathomimetic-containing products may act as cerebral stimulants giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions

Concurrent use with halogenated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane or isoflurane may provoke or worsen ventricular arrhythmias

Contains aspartame (E951) a source of phenylalanine equivalent to 29.7 mg/dosage unit. May be harmful for people with phenylketonuria.

Contains sucrose. The content of sucrose on a daily basis of four doses is 9.40g. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine

Contains carmoisine (E122). May cause allergic reactions

Do not exceed the stated dose.

Patients should be advised not to take with other paracetamol containing products. The physician or pharmacist should check that sympathomimetic containing preparations are not simultaneously administered by several routes, i.e. orally and topically (nasal, aural and eye preparations).

4.5 Interaction with other medicinal products and other forms of interaction

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

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.

Paracetamol increases the plasmatic levels of acetylsalicylic acid and chloramphenicol. Only short-term concomitant administration with acetylsalicylic acid is possible because of the increased risk of renal impairment similar to that caused by other non-steroid anti-inflammatory drugs.

Probenecid causes an almost 2-fold reduction in clearance of Paracetamol by inhibiting its conjugation with glucuronic acid. A reduction of the Paracetamol dose should be considered for concomitant treatment with probenecid.

Concurrent use of Paracetamol and AZT (zidovudine) increases the disposition to neutropenia. Therefore, concomitant use of paracetamol with AZT requires medical advice.

Phenylephrine may adversely interact with other sympathomimetics, vasodilators, and β - blockers. Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Not recommended for patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.

4.6 Fertility, 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 contraindicate breast feeding.

There are limited data on the use of phenylephrine in pregnant women. Vasoconstriction of uterine vessels and reduced uterine blood flow associated with the use of phenylephrine may result in foetal hypoxia. Until more information is available, use of phenylephrine should be avoided during pregnancy.

There is no data available on whether phenylephrine is released into breast milk and no reports on the effects of phenylephrine on the nursing infant. Until more data are available, caution is necessary when considering the use of phenylephrine in lactating women

4.7 Effects on ability to drive and use machines

Paracetamol 1000mg, phenylephrine hydrochloride 12.2mg, Powder for oral solution, blackcurrant flavour has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness

Blood and the lymphatic system disorders (very rare $\leq 1/10,000$) blood dyscrasias e.g. thrombocytopenia, agranulocytosis, haemolytic anaemia, neutropenia, leucopenia, pancytopenia

Immune system disorders (rare $\geq 1/10,000$ to $\leq 1/1000$) allergic or hypersensitivity reactions, including anaphylaxis and bronchospasm, urticaria and skin rashes

Nervous system disorders (rare $\geq 1/10,000$ to $\leq 1/1000$) insomnia, nervousness, tremor, anxiety, restlessness, confusion, irritability and headache.

Cardiac disorders (rare $\geq 1/10,000$ to $\leq 1/1000$) tachycardia

Vascular disorders (rare $\geq 1/10,000$ to $\leq 1/1000$) high blood pressure with palpitations, headache and vomiting.

Gastrointestinal disorders (common $\geq 1/100$ to $< 1/10$) anorexia, nausea and vomiting

Hepatobiliary disorders: Liver function test abnormal (elevation of hepatic aminotransferase levels)

Skin and subcutaneous tissue disorders (rare $\geq 1/10,000$ to $\leq 1/1000$) hypersensitivity including skin rash and urticaria.

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 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.

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 local Poison Control Centre 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 IV α -receptor blocking agent.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Paracetamol combinations excluding psycholeptics

ATC code: N02BE51

Paracetamol: Paracetamol has both analgesic and antipyretic activity which is believed to be mediated principally through its inhibition of prostaglandin synthesis in the central nervous system.

Phenylephrine hydrochloride: Phenylephrine is a post-synaptic α -receptor agonist with low cardioselective α -receptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

5.2 Pharmacokinetic properties

Paracetamol is absorbed rapidly and completely mainly from the small intestine, producing peak plasma levels after 15-20 minutes following oral dosing. The systemic availability is subject to first-pass metabolism and varies with dose between 70% and 90%. The drug is rapidly and widely distributed throughout the body and is eliminated from plasma with a half-life of approximately 2 hours. The major metabolites are glucuronide and sulphate conjugates (> 80%) which are excreted in the urine.

Phenylephrine hydrochloride is rapidly absorbed from the gastro-intestinal tract. Presystemic metabolism is high at about 60%, resulting in systemic bioavailability of about 40%. Peak plasma levels occur between 1 and 2 hours and the plasma half-life ranges from 2 – 3 hours. When taken by mouth as a nasal decongestant phenylephrine is usually given at intervals of 4 – 6 hours.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium citrate
Citric acid
Ascorbic acid
Acesulfame Potassium
Aspartame
Blackcurrant Flavour Permaseal S-133747
Blackcurrant Flavour 1007348
Euroblend Blackcurrant Shade*

*Contains Carmoisine and Brilliant Blue

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

This product is packed in laminate sachets comprising paper/polyethylene/aluminium foil/ polyethylene.
Five or ten sachets are contained in a boxboard carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Procter & Gamble (Health & Beauty Care) Ltd.
The Heights
Brooklands
Weybridge
Surrey KT13 0XP
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 441/41/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th December 2011

10 DATE OF REVISION OF THE TEXT