

PARTAMOL-CAFEIN EFFERVESCENT TABLETS

1. **Name of the medicinal product**
PARTAMOL-CAFEIN EFFERVESCENT TABLETS
2. **Special notice and recommendation**
Keep out of reach of children
Read the package insert carefully before use
3. **Composition**
Each effervescent tablet contains:
Paracetamol 500 mg
Caffeine 65 mg
4. **Pharmaceutical form**
Effervescent tablet.
White to almost white, round tablet, flat and plain on both sides.
When dissolved in water, the tablet effervesces to produce a colorless solution with characteristic aroma.
5. **Indications**
PARTAMOL-CAFEIN EFFERVESCENT TABLETS is a mild analgesic and antipyretic formulated to give extra pain relief. The soluble tablets are recommended for the treatment of most painful and febrile conditions, for example, headache including migraine, backache, toothache, colds and influenza, sore throat, rheumatic pain and dysmenorrhoea.
6. **Administration and dosage**
Administration
PARTAMOL-CAFEIN EFFERVESCENT TABLETS are for oral administration only. The tablets should be dissolved in at least half a tumblerful of water.
Dosage
Adults (including the elderly) and children aged 16 years and over:
 - Two tablets up to four times daily.
 - Do not exceed 8 tablets in 24 hours.Children aged 12-15 years:
 - One tablet up to four times daily.
 - Do not exceed 4 tablets in 24 hours.
 - Not recommended for children under 12 years.
 - Do not take more frequently than every 4 hours.
 - Do not take for longer than three days without consulting your doctor.
7. **Contraindications**
Hypersensitivity to paracetamol, caffeine or any of the other constituents.
8. **Special warnings and precautions for use**
 - Avoid other caffeine containing products. Too much caffeine may cause rapid heart rate, nervousness or sleeplessness.
 - Ask a doctor or pharmacist before use if you have high blood pressure, glaucoma, or overactive bladder syndrome.
 - Do not exceed 8 tablets in 24 hours.
 - Do not take more than the recommended dose unless advised by your doctor. Use the smallest effective dose. Taking more than the maximum daily dose may cause severe or possibly fatal liver damage.
 - Do not use with other drugs containing paracetamol.
 - Not recommended for children under 12 years.
 - Unsuitable for phenylketonurics.
 - Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.
 - Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.
 - Caution should be exercised in patients with glutathione depleted states, as the use of paracetamol may increase the risk of metabolic acidosis (see section 13).
 - If symptoms persist, medical advice must be sought.
 - Keep out of the sight and reach of children.
9. **Pregnancy and lactation**
Pregnancy
PARTAMOL-CAFEIN EFFERVESCENT TABLETS is not recommended for use during pregnancy due to the possible increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption.
Lactation
Caffeine in breast milk may potentially have a stimulating effect on breast fed infants.
Due to the caffeine content of this product it should not be used if you are pregnant or breast feeding.

10. Effects on ability to drive and use machines

None.

11. Drug interactions

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. Caffeine may increase clearance of lithium. Concomitant use is therefore not recommended.

12. Adverse reactions

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Adverse reactions identified during post-marketing use are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown but likely to be very rare (<1/10,000).

Paracetamol

- **Blood and lymphatic:** Thrombocytopenia, agranulocytosis.
- **Immune:** Very rare cases of serious skin reactions have been reported, anaphylaxis, cutaneous hypersensitivity reactions including (amongst others) skin rashes and angioedema.
- **Respiratory, thoracic and mediastinal:** Bronchospasm- more likely in patients sensitive to aspirin and other NSAIDs.
- **Hepatobiliary:** Hepatic dysfunction.

Caffeine

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects.

- **Central nervous system:** Dizziness, headache.
- **Cardiac:** Palpitation.
- **Psychiatric:** Insomnia, restlessness, anxiety and irritability.
- **Gastrointestinal:** Gastrointestinal disturbances.

13. Overdosage and management

Paracetamol

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors:

If the patient

- Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

- Regularly consumes ethanol in excess of recommended amounts.

Or

- 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, 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.

Caffeine

Symptoms

Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions).

It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related toxicity.

Management

Patients should receive general supportive care (e.g. hydration and maintenance of vital signs). The administration of activated charcoal may be beneficial when performed within one hour of the overdose, but can be considered for up to four hours after the overdose. The CNS effects of overdose may be treated with intravenous sedatives.

14. Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics; Anilides; Paracetamol, combinations excl. psycholeptics.

ATC code: N02BE51

The combination of paracetamol and caffeine is a well established analgesic combination.

15. Pharmacokinetic properties

- Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. It is relatively uniformly distributed

throughout most body fluids and exhibits variable protein binding. Excretion is almost exclusively renal, in the form of conjugated metabolites.

- Caffeine is absorbed readily after oral administration, maximal plasma concentrations are achieved within one hour and the plasma half-life is about 3.5 hours. 65 - 80% of administered caffeine is excreted in the urine as 1-methyluric acid and 1-methylxanthine.

16. Packaging

Strip of 4 tablets. Box of 8 strips.

17. Storage condition, shelf-life

Protect from light and moisture. Do not store above 30°C.

The expiry date of this pack is printed on the box. Do not use this pack after this date.

18. Distributed by

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