Pharmacode

32.5 mm

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Aetos

PANELIEF EFFERVESCENT TABLET 500MG

1. Name of the medicinal product
Panelief Effervescent Tablet 500mg

2. Qualitative and quantitative composition
Each effervescent tablet contains
Paracetamol 500 mg

3. Pharmaceutical form
Effervescent tablet.
White to off-white, round tablet, flat and plain on both sides. When dissolved in water, the tablet effervesces to produce a colorless solution with characteristic aroma.

4. Clinical Particulars
4.1 Therapeutic indications
Paracetamol is a mild analgesic and antipyretic, and is recommended for the treatment of most painful and febrile conditions, for example, headache including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat, and for relieving the fever, aches and pains of colds and flu.

4.2 Posology and method of administration
Administration
Oral administration only.

Dosage
Adults, the elderly, and children aged 12 years and over:
1 -2 tablets in at least half a glass of water, up to 4 times daily every 4 to 6 hours as required, up to 8 tablets daily.

Children:
Aged 9-11 years: 1 tablet dissolved in at least half a glass of water.
Maximum daily dose: 60mg/kg paracetamol to be administered in divided doses throughout the 24-hour period. Doses of paracetamol should not be given more frequently than every 4 hours, and not more than 4 doses should be given in any 24 hour period.
Not recommended for children under the age of 9 years.

4.3 Contraindications
Hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

This preparation contains PARACETAMOL.
Do not take any other paracetamol containing medicines at the same time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.
• Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.
• Do not exceed the stated dose.
• Patients should be advised to consult their doctor if their headaches become persistent.
• Patients should be advised to consult a doctor if they suffer from nonserious arthritis and need to take painkillers every day.
• Patients should be advised to consult a doctor if they are underweight or malnourished before use.
• Patients should be advised to consult a doctor if they regularly drink alcohol before use.
• Patients should be advised to consult a doctor before use if they have a severe infection as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include: shallow, rapid, difficult breathing, feeling sick (nausea), being sick (vomiting), loss of appetite.
• Each effervescent tablet contains 329 mg of sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.
• If symptoms persist, medical advice must be sought.
• Keep out of the sight and reach of children.
• This product contains aspartame. Unsuitable for phenylketonurics.

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 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.

4.6 Fertility, pregnancy and breast-feeding
Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy, however, as with any medicine it should be used at the lowest effective dose for the shortest possible time.
Paracetamol is excreted in breast milk but not in a clinically significant amount in recommended dosages. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines
None

4.8 Undesirable effects
Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure.
Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class and frequency. The following convention has been utilised for the classification of the undesirable effects: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).
Adverse event frequencies have been estimated from spontaneous reports received through post-marketing data.

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Blood and lymphatic system disorders
Very rare: Thrombocytopenia, agranulocytosis.
Immune system disorders
Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.
Respiratory, thoracic and mediastinal disorders
Very rare: Bronchospasm *
Hepatobiliary disorders
Very rare: Hepatic dysfunction
*There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

4.9 Overdose
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.

High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. In addition, high doses of sodium bicarbonate may cause hypernatraemia; electrolytes should be monitored and patients managed accordingly.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other analgesics and antipyretics; anilides.
ATC code: N02BE01.
Paracetamol is a well-established analgesic.

5.2 Pharmacokinetics properties
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Concentration of the drug in plasma reaches a peak in 30 - 60 minutes and the plasma half-life is 1 - 4 hours. Paracetamol is relatively uniformly distributed throughout most body fluids and exhibits variable protein binding. Excretion is almost exclusively renal in the form of conjugated metabolites

6. Pharmaceutical particulars
6.1 List of excipients
Citric acid anhydrous, Sodium bicarbonate, Sodium carbonate anhydrous, Povidone K30, Macrogol 6000, Sodium benzoate, Saccharin sodium, Aspartame, Lemon lime flavour

6.2 Special precautions for storage
Store below 30°C. Protect from light and moisture.

6.3 Nature and contents of container
Strip of 4 tablets. Box of 4 strips.

7. Manufacturer
Stellapharm J.V. Co., Ltd. - Branch 1
(A Joint Venture Company of Auxilto GmbH, Germany)
No. 40 Tu Do Avenue, Vietnam – Singapore Industrial Park, An Phu Ward, Thuan An City, Binh Duong Province, Vietnam.

8. Marketing authorization holder
Aetos Pharma Sdn Bhd
66B, Tingkat 2, Jalan Cerdas, Taman Connaught, 56000 Kuala Lumpur, Malaysia.

9. Date of revision of the text
12 June 2025