THROZZ Paracetamol 500mg Tablet

NAME AND STRENGHT OF ACTIVE SUBSTANCE

Each uncoated tablet contains: Paracetamol BP 500mg.

DESCRIPTION

White, capsule shaped tablet. Plain on one side with a break line on the other side.

PHARMACODYNAMICS

Pharmacotherapeutic group: Other analgesics and antipyretics, Anilides.
ATC code: N02BE01

Mechanism of action
Paracetamol is a type of analgesic and antipyretic. Its mechanism of action is believed to include the inhibition of prostaglandin synthesis, particularly in the central nervous system.

Pharmacodynamic effects
Lack of peripheral prostaglandin inhibition results in important pharmacological properties such as preservation of protective prostaglandins in the gastrointestinal tract. Therefore, paracetamol is particularly suitable for patients with a history of illness or who are taking concomitant medications, where peripheral prostaglandin inhibition is not required (such as, for example, those with a history of gastrointestinal bleeding or the elderly).

PHARMACOKINETICS

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is 1 - 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 30% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 - 100% of the drug may be recovered in the urine within the first day. However, practically no paracetamol is excreted unchanged and the bulk is excreted after hepatic conjugation.

INDICATION

For relief of fever, pain and headache.

RECOMMENDED DOSAGE

Adults, elderly and children aged 12 and above:
1-2 tablets (500mg – 1000mg), every 4 to 6 hours when necessary with a maximum of 8 doses in 24 hours.

Children 6 to 11 years:
0.5-1 tablet (250-500mg) every 4 to 6 hours with a maximum of 4 doses in 24 hours.

Do not exceed the recommended dose
The lowest effective dose and the shortest duration of treatment should be used.
Interval between doses is a minimum of 4 hours.

Renal Impairment
Patients diagnosed with kidney problems must seek medical advice before taking this medicine. Limitations related to the use of paracetamol in patients with kidney problems are a result of the content of paracetamol in the medicine.

Liver impairment

Patients diagnosed with liver problems must seek medical advice before taking this medicine. Limitations related to the use of paracetamol in patients with liver problems are a result of the content of paracetamol in the medicine.

ROUTE OF ADMINISTRATION

Oral

CONTRAINDICATIONS

Hypersensitivity to paracetamol or any other ingredient of the tablet.

WARNING AND PRECAUTIONS

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 the use and seek medical assistance immediately.

- Do not take if allergic to paracetamol
- Underlying liver or kidney disease increases the risk of paracetamol related liver or kidney 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 non-serious arthritis and need to take painkillers every day.
- Caution should be exercised in patients with glutathione depleted states, as the use of paracetamol may increase the risk of metabolic acidosis.
- Use with caution in patients with glutathione depletion due to metabolic deficiencies.
- If symptoms persist, medical advice must be sought.
- Keep out of the sight and reach of children.

INTERACTIONS WITH OTHER MEDICINES

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.

PREGNANCY AND LACTATION

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 breastfeeding.

SIDE 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 listed below:

Blood and lymphatic system disorders
Very rare: Thrombocytopenia; Agranulocytosis.

Immune system disorders

Very rare: Anaphylaxis.
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.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. 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.
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 overdosage 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.

PRESENTATION

Blister of 10 tablets. Box of 2 x 10s, 3 x 10s, 5 x 10s, 10 x 10s, 50 x 10s, 100 x 10s tablets.

STORAGE CONDITION

Store below 30°C
Protect from light and moisture. Keep out of reach of children.

SHELF LIFE

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

PRODUCT REGISTRATION HOLDER

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