

pharmaniaga[®]

IDAMOL TABLET 500MG

PRODUCT DESCRIPTION

Clean, dry, round, biconvex tablet and scored on one side and white in colour.

Each tablet contains: Paracetamol 500mg

PHARMACODYNAMICS

Pharmacotherapeutic group: Other analgesics and antipyretics, Anilides

ATC code N02B E01

Paracetamol is an antipyretic analgesic with weak anti-inflammatory activity. The mechanism of action is probably similar to that of aspirin. Paracetamol is involved in prostaglandin synthesis in the CNS to a lesser extent through a peripheral action by blocking pain-impulse generation. This inhibition appears, however to be on a selective basis. Paracetamol probably produces an antipyretic action by a central effect on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus. The drug has no effect on the cardiovascular and respiratory systems, and unlike salicylates, it does not cause gastric irritation or bleeding.

PHARMACOKINETICS

Absorption

Paracetamol is readily absorbed from the gastrointestinal tract. Peak plasma concentration is achieved within 10-60mins. The plasma half-life is 1-4 hours after therapeutic doses.

Distribution

Paracetamol is uniformly distributed throughout body tissues. It crosses the placenta and is present in breast milk. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Biotransformation

Paracetamol metabolism takes place in the liver. A very small amount of minor hydroxylated metabolite is produced by mixed-function oxidases in liver. It is usually detoxified by conjugation with liver glutathione due to paracetamol overdose which can lead to tissue damage.

Elimination

90-95% is excreted in urine as glucuronide and sulphate conjugate. Less than 5% is excreted as unchanged paracetamol. The elimination half-life is approximately 1-4 hours.

INDICATION

For the relief of fever.

For the relief from mild to moderate pain including: headache, migraine, backache, musculoskeletal pain, myalgia and neuralgia, dysmenorrhea, pain of osteoarthritis, toothache, pain after dental procedures/tooth extraction, pain after vaccination and the discomfort from colds, influenza and sore throats.

RECOMMENDED DOSAGE

Adults and children aged 12 years and over:

1 to 2 tablets taken every 4 to 6 hours as required up to maximum of 8 tablets daily.

Children

6 to 11 years:

1/2 to 1 tablet every 4 to 6 hours as required.

Maximum daily dose: 60mg/kg presented in divided doses of 10-15mg/kg throughout 24-hour period.

ROUTE OF ADMINISTRATION

Oral

CONTRAINDICATIONS

Hypersensitivity to paracetamol or any of the other ingredients / components of the product. Severe and active hepatic impairment.

WARNINGS AND PRECAUTIONS

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

- Keep out of reach of children.
- Do not take if allergic to paracetamol.
- **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.
- Patients should contact their health care provider if symptoms persist (if the pain lasts for more than 10 days, if there is redness or fever lasts more than 3 days).
- Care is also advised in the administration of paracetamol to patients with alcohol dependency, severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Underlying liver disease increases the risk of paracetamol related liver damage. Patients must seek medical advice before taking this medication.
- Large doses should be avoided in patients with hepatic impairment.
- Paracetamol overdose may harm the liver.
- Do not exceed recommended dose.
- Paracetamol provides symptomatic relief only, additional therapy to treat the cause of the pain or fever should be instituted when necessary.
- Patients should be advised to consult a doctor if they suffer from non-serious arthritis and need to take painkillers everyday.
- 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.
- Where analgesics are used long-term (>3 months) with administration every two days or more frequently, headache may develop or worsen. Headache induced by overuse of analgesics (MOH medication-overuse headache) should not be treated by dose increase. In such cases, the use of analgesics should be discontinued in consultation with the doctor.
- Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.
- Patients should be advised to consult their doctor if their headaches become persistent.

INTERACTIONS WITH OTHER MEDICAMENTS

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.

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

Regular concomitant use of paracetamol and imatinib should be restricted or avoided.

PREGNANCY AND LACTATION

Use in pregnancy:

- Considered to be the analgesic of choice in pregnant patients.
- Although it crosses placenta, paracetamol is considered to be safe in normal therapeutic doses for short-term use as a minor analgesic/antipyretic in pregnancy. If paracetamol is clinically needed during pregnancy, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Use in lactation:

- Excreted in breast milk but not in a clinically significant amount.
- Maternal ingestion of paracetamol in normal therapeutic doses does not appear to present a risk to the nursing infant.

ADVERSE EFFECTS / UNDESIRABLE EFFECTS

Adverse effects of paracetamol are rare and usually mild, although haematological reactions have been reported. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Steven Johnson Syndrome/ Toxic Epiderma Necrolysis have been reported.

Body System	Adverse Effects/ Undesirable effect
Blood and lymphatic system disorders	There have been reports of blood dyscrasias including thrombocytopenia, neutropenia, pancytopenia, leukopenia and agranulocytosis but these were not necessarily causality related to paracetamol.
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes and angioedema. Very rare cases of serious skin reactions have been reported.
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs

OVERDOSE AND TREATMENT

Symptoms:

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.

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.

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;

c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

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:

In cases of overdose, methods of reducing the absorption of ingested drug are important. Gastric lavage is essential even if several hours have elapsed. Prompt administration of 50g activated charcoal and 500ml iced mannitol 20% by mouth, may reduce absorption. If the history suggests that 15g Paracetamol or more has been ingested, administer one of the following antidotes:

Acetylcysteine 20% i.v.: Administer intravenously, 20% acetylcysteine immediately without waiting for positive urine test or plasma level results: initial dose of 150mg/kg over 15 minutes, followed by continuous infusion of 50mg/kg in 500ml 5% glucose /dextrose over 4 hours and 100mg/kg in 1L 5% glucose/dextrose over 16 hours;

OR

Oral Methionine: 2.5g immediately followed by three further doses of 2.5g at four hourly intervals. For a 3 year old child, 1g methionine every four hours doses has been used;

OR

Oral Acetylcysteine 5%: 140mg/kg as a loading dose, then 70mg/kg every 4 hours for a total of 17 maintenance doses. If more than ten hours have elapsed since the overdosage was taken, the antidote may be ineffective.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

It is unlikely to impair a patient's ability to drive or use machinery.

STORAGE CONDITIONS

Keep in a dry place, below 30°C; Protect from light.

PACKING/PACK SIZE

Blister Pack of 10's (100 strips of 10 tablets).

SHELF-LIFE:

Product should not be used beyond the expiry date imprinted on the product packaging.

REGISTRATION NO:

MAL20046150XZ

KEEP MEDICINES OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK

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PRODUCT REGISTRATION HOLDER AND MANUFACTURER

INSPIRAPharma SDN. BHD. (200401023395)

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