HOVID ADAMOL FILM-COATED TABLETS 500MG

eVIADA01-var1 (MY)

DESCRIPTION
White to off white colored, circular, biconvex film coated tablets with break-line on one side and embossed with 'H' on other side.

COMPOSITION
Each tablet contains Paracetamol B.P. 500 mg.

PHARMACODYNAMICS
Analgesic – The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain – impulse generation.

The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

Antipyretic – Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulation center 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.

PHARMACOKINETICS
Absorption
Paracetamol is readily absorbed from the gastrointestinal tract.

Distribution
Peak plasma concentrations occur about 10 to 60 minutes after oral doses. Paracetamol is distributed into most 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
It is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause tissue damage.

Elimination
It is excreted in the urine, mainly as the glucuronide and sulfate conjugates. The elimination half-life varies from about 1 to 4 hours.

INDICATIONS
Hovid Adamol Film-Coated Tablets is for the relief of fever and the relief from mild to moderate pain including: headache, migraine, backache, musculoskeletal pain, period pain, pain of osteoarthritis, toothache, pain after dental procedures/tooth extraction, pain after vaccination and the discomfort from colds, influenza and sore throats.

CONTRAINDICATIONS
Hovid Adamol Film-Coated Tablets is contraindicated in hypersensitivity to paracetamol or any of the constituents.

WARNINGS AND PRECAUTIONS
Contains paracetamol. Do not use with any other paracetamol-containing products.

Underlying liver disease increases the risk or 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 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 (refer also to section 4.9).

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.

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.

PREGNANCY AND LACTATION
There is no ill effects due to paracetamol used in the recommended dosage in pregnancy, but patients should follow the advice of the 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

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
The effects of Hovid Adamol Film-Coated Tablets on the ability to drive and use machine is not known yet.

INTERACTION WITH OTHER MEDICATIONS AND OTHER FORMS OF INTERACTION

- Anticoagulants - the effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding. Occasional doses have no significant effect.
- Metoclopramide - may increase speed of absorption of paracetamol.
- Domperidone - may increase speed of absorption of paracetamol.
- Colestyramine - may reduce absorption if given within one hour of paracetamol.
- Imatinib - restriction or avoidance of concomitant regular paracetamol use should be taken with imatinib.

MAIN SIDE/ ADVERSE EFFECTS

Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia, neutropenia, pancytopenia, leukopenia and agranulocytosis but these were not necessarily causality related to Paracetamol

Very rare cases of serious skin reactions have been reported.

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

OVERDOSE

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors such as if the patient is on term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, Rifampicin, St john's wort or other drugs that induce liver enzymes or if patient regularly consumes ethanol in excess of recommended amount or if patient 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, hemorrhage, hypoglycemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by joint pain, hematuria 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 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.

If required the patient should be given intravenous N-acetylcysteine, in line with 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 24 hours from ingestion should be discussed with the NPIS or a liver unit.

DOSAGE AND ADMINISTRATION

Adults (including the elderly) and children aged 12 years and over: 500mg to 1000mg paracetamol (1 to 2 tablets), taken every 4 to 6 hours as required.

Children under 12 years: Not recommended for children under the age of 12 years.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Oral administration only.

Minimum dosing interval: 4 hours

Maximum daily dose: 4000mg (8 tablets)

Storage : Store below 30°C. Protect from light.

Presentation/ packing : Blister of 10 x 10's

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