

Temol[®]

Paracetamol

COMPOSITION:

Temol[®] 500 Tablet: Each film coated tablet contains Paracetamol BP 500 mg.

Temol[®] Extra Tablet: Each film coated tablet contains Paracetamol BP 500 mg & Caffeine USP 65 mg.

Temol[®] XR Tablet: Each extended release tablet contains Paracetamol BP 665mg.

Temol[®] Suspension: Each 5 ml suspension contains Paracetamol BP 120 mg.

PHARMACOLOGY:

Paracetamol is a clinically proven analgesic and antipyretic. Paracetamol is equivalent to Aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce many of the side effects associated with Aspirin and Aspirin-containing drugs. Paracetamol has greater tissue selectivity than Aspirin and other NSAIDs.

INDICATION:

Paracetamol is indicated for the temporary relief of minor aches and pains associated with influenza, headache, toothache, earache, pain due to neurological disturbance, for the pain of menstrual cramps, for the minor pain of arthritis and for the reduction of fever.

DOSE & ADMINISTRATION:

For Tablet:

Adults: 0.5-1gm (1-2 tablets) every 4-6 hours. Maximum daily dose is 4 gm (8 tablets).

For Extended release Tablet:

Adult and children over 12 years: 2 tablets swallowed whole, every 6-8 hours (maximum 6 tablets per day). The tablet must not be crushed.

For Suspension:

Children: For post immunization pyrexia 60 mg followed if necessary by a second dose 4 to 6 hours later. Under 3 months (on doctor's advice only) : 10 mg/kg body weight (5 mg/kg body weight if jaundiced) 3-4 times daily. Shake the bottle before each use.

CONTRA-INDICATION:

Paracetamol should not be given to the patients with severe hepatic and renal impairment and hypersensitivity to its components.

WARNING AND PRECAUTION:

This drug should be given with precaution in patients with hepatic and renal problem. Paracetamol should not be taken in pain for more than 10 days or in fever for more than 3 days unless directed by a physician.

SIDE EFFECTS:

Side effects are rare. Liver damage may occur following overdose. The primary symptoms of liver damage are nausea, vomiting and physical discomfort.

USE IN PREGNANCY & LACTATION:

Use in pregnancy:

Considered to be the analgesic of choice for pregnant patients. Although it crosses placenta, Paracetamol is considered to be safe in normal therapeutic doses for short-term use as a minor analgesic and antipyretic in pregnancy.

Use in lactation:

Excreted in breast milk. Maternal ingestion of Paracetamol in normal therapeutic doses does not appear to present a risk to the nursing infant.

USE IN CHILDREN & ADOLESCENTS:

Paracetamol 500 mg & Paracetamol 665 mg tablets are not recommended for use in children below 4 years or below 17 kg body weight, as the dosage strength is not suitable for this age group. However, there are appropriate dosage strengths and formulations available for this age group.

DRUG 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.

OVERDOSE:

Toxic symptoms include vomiting, abdominal pain, hypotension and sweating. The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal hepatic necrosis. Clinical and laboratory evidence of hepatotoxicity may be delayed for up to one week. Major manifestations of liver failure such as jaundice, hypoglycemia and metabolic acidosis may take at least 3 days to develop.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Temol[®] 500 mg Tablet: Each box contains 20 x 10's tablets in a Alu-PVC blisters pack.

Temol[®] Extra Tablet: Each box contains 20 x 10's tablets in a Alu-PVC blisters pack.

Temol[®] XR Tablet: Each box contains 12 x 10's tablets in a Alu-PVC blisters pack.

Temol[®] Suspension: Each bottle contains 60 ml suspension with a measuring spoon.



Manufactured by

Team Pharmaceuticals Ltd.

B 75-79, BSCIC, Rajshahi, Bangladesh

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