Dolopan®

Paracetamol

FORMS AND PRESENTATION
Dolopan®: Film coated tablets: Box of 20.
COMPOSITION
Dolopan®: Each film coated tablet contains Paracetamol 500mg.
Excipients: starch, stearic acid, povidone, hydroxypropyl methylcellulose, titanium dioxide, talc, polyethylene glycol.
PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Therapeutic class: Analgesics.
ATC code: N02BE01.
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.
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.
Pharmacokinetic properties
Absorption
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.
Distribution
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.
Biotransformation
Paracetamol is metabolized 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 liver damage.
Elimination
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.
INDICATIONS
Dolopan® 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, dysmenorrhea, sore throat, and for relieving the fever, aches and pains of colds and flu. Dolopan® is also recommended for the symptomatic relief of pain due to non-serious arthritis.
CONTRAINDICATIONS
- Hypersensitivity to Paracetamol or any of the constituents.
PRECAUTIONS
- Care is advised in the administration of Paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.
- Do not exceed the stated dose.
- Patients should be advised to consult their doctor if their headaches become persistent.
- Patients should be advised not to take other Paracetamol-containing products concurrently.
- Patients should be advised to consult a doctor if they suffer from non-serious arthritis and need to take painkillers every day.
- If symptoms persist consult your doctor.
- Keep out of the reach and sight of children.
- Immediate medical advice should be sought in the event of an overdose, even if you feel well.
Ability to drive and use machines
No effects on the ability to drive and use machines are known.
PREGNANCY AND LACTATION
Epidemiological studies in human pregnancy have shown no ill effects due to Paracetamol used in the recommended dosage, 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.
DRUG INTERACTIONS
- Cholestyramine: The speed of absorption of Paracetamol is reduced by cholestyramine. Therefore, cholestyramine should not be taken within one hour if maximal analgesia is required.
- Metoclopramide and domperidone: The absorption of Paracetamol is increased by metoclopramide and domperidone. However, concurrent use need not be avoided.
- Warfarin: The anticoagulant 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.
- Chloramphenicol: Increased plasma concentration of chloramphenicol.

ADVERSE EFFECTS
Adverse effects of Paracetamol are rare. Reported adverse reactions are listed below by body system:
- Blood and lymphatic system disorders: Thrombocytopenia and agranulocytosis.
- Immune system disorders: Anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens-Johnson syndrome / toxic epidermal necrosis.
- Respiratory, thoracic and mediastinal disorders: Bronchospasm. There have been cases of bronchospasms with Paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.
- Hepatobiliary disorders: Hepatic dysfunction.
DOSAGE AND ADMINISTRATION
Adults
Two tablets up to four times daily as required.
Children
6 - 12 years: Half to one tablet three or four times daily as required. Not suitable for children under six years of age. Children should not be given Dolopan® for more than 3 days without consulting a doctor.
These doses should not be repeated more frequently than every four hours nor should more than four doses be given in any 24 hour period.
Oral administration only.
OVERDOSAGE
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, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- If the patient regularly consumes ethanol in excess of recommended amounts.
- If the patient is likely to be glutathione depleted 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 edema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin 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 the 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 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.
- 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 the hospital.
- Management of patients who are presented with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with a liver unit.
STORAGE CONDITIONS
Store below 30°C.
Keep in original pack in intact conditions.

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This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
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