

PACKAGE INSERT

Remedol



ANALGESIC, ANTIPYRETIC, ANTI-INFLAMMATORY

Packs

Tablets (scored)	500mg	20
Fruit flavoured		
Suspension	120mg/5ml	100ml
Fruit flavoured		
Suspension	250mg/5ml	100ml
Suppositories	125mg	10
Suppositories	250mg	10
Suppositories	500mg	10

Composition

The active ingredient of Remedol is Paracetamol.

Properties

Remedol has analgesic and antipyretic properties. Analgesia is produced by elevation of the pain threshold and antipyresis through action on the hypothalamic heat-regulating center. Paracetamol is equal to Aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce many of the side-effects associated with Aspirin. Remedol does not cause gastric irritation, is well absorbed and is effective for about 4 hours. It is metabolized in the liver.

Indications

Remedol tablets are indicated for the treatment of most painful and febrile conditions, for example, headache, toothache, colds, influenza, rheumatic pain and dysmenorrhoea.

Remedol suspension is indicated for the treatment of mild to moderate pain (including teething pain), and as antipyretic. Remedol suppositories are indicated for the treatment of conditions associated with fever and pain in children and infants such as tonsillitis, headache, reactions after vaccination, colds, influenza, myalgia and pain following tonsillectomy.

Dosage

Remedol Tablets

Adults: One to two tablets up to four times a day, as required.

Elderly: As for adults but see precautions.

Children 6-12 years: Half to one tablet up to four times a day.

Remedol Suspension 120mg/5ml

Children 1-6 years: One to two 5ml spoonfuls (120-240mg).

Children 3 months to 1 year: Half to one 5ml spoonful (60-120mg).

Infants under 3 months: Half 5ml spoonful is suitable for babies who develop fever following vaccination at 2 months. In other cases to be used only under medical supervision.

Remedol Suspension 250mg/5ml

Adults and Children over 12 years: Two to four 5ml spoonfuls.

Children 6 to 12 years: One to two 5ml spoonfuls (250-500mg).

Children 1 to 6 years: Half to one 5ml spoonful (125-250mg).

Infants under 3 months: Not recommended.

Remedol Suppositories

Infants under 3 months: As instructed by the physician.

Children 3 to 6 months: One suppository of 125mg, 2-3 times daily.

Children 6 to 12 months: One suppository of 125mg, 3-4 times daily.

Children 1 to 5 years: One suppository of 250mg repeated every 4-6 hours when necessary (maximum of 4 doses in 24 hours).



Children 6 to 12 years: One suppository of 500mg repeated every 4-6 hours when necessary (maximum of 4 doses in 24 hours). Remedol Suppositories may liquefy if stored at temperatures greater than 35°C. In such cases cool with cold water or in a refrigerator before opening the plastic container; the quality of the suppositories is not affected at all.

These dosages may be repeated as required, but should be given no more frequently than every 4 hours. Not more than 4 doses should be taken in any 24 hours.

Side-effects

The side-effects of Remedol are usually mild, though haematological reactions have been reported. Skin rashes and other allergic reactions may occur occasionally. Most reports of side-effects to Remedol relate to overdosage with the drug. Doses exceeding 7g may cause hepatic damage and larger doses may cause hepatic necrosis.

Warnings and Precautions

Remedol should be administered with caution to patients with hepatic or renal impairment.

Serious skin reactions

Rarely, paracetamol may cause serious skin reactions such as acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Pregnancy:

There is epidemiological evidence of the safety of Paracetamol in human pregnancy.

Breast-feeding:

Maternal ingestion of therapeutic doses of Paracetamol does not present a risk to the infant.

Drug Interactions:

Paracetamol absorption is reduced by Cholestyramine. The half-life of Chloramphenicol is prolonged by Paracetamol. The absorption rate of Paracetamol is increased by Metoclopramide.

Contra-indications

Remedol is contra-indicated in patients with known hypersensitivity to Paracetamol.

Overdosage

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. Liver damage is likely in adults who have taken 10g or more of Paracetamol. Prompt treatment is essential in the management of Paracetamol overdosage. Any patient who has ingested 7.5g or more of Paracetamol should undergo gastric lavage. Specific therapy with an antidote such as Acetylcysteine or Methionine may be necessary. Acetylcysteine may be given by mouth.

Pharmaceutical Precautions

Storage Conditions:

Remedol should be stored below 25°C, protected from light and moisture.

Incompatibilities:

None.

Information

The information contained in this leaflet is limited and further information can be obtained from other sources, including doctors and pharmacists.

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www.remedica.eu

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Remedol

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N.S.

Final Size: 157 x 165mm

Colours: Black



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