P18/0065 AS3

Remethan™

ANALGESIC, ANTIPYRETIC, ANTI-INFLAMMATORY

Packs		
Enteric-coated tablets	25mg	30
Enteric-coated tablets	50mg	20
Retard tablets	100mg	10, 30
Suppositories	100mg	5

Composition

The active ingredient of Remethan is Diclofenac Sodium.

Properties

Remethan is a non-steroidal phenylacetic acid derivative which has marked analgesic, antipyretic and anti-inflammatory properties. Remethan is absorbed from the gastro-intestinal tract reaching peak plasma concentrations in two hours after ingestion of the enteric-coated tablets. Remethan is metabolised and excreted mainly in the urine.

Indications

Remethan is indicated for the treatment of rheumatoid arthritis, ankylosing spondylitis, osteoarthrosis, low back pain, frozen shoulder, tendinitis, tenosynovitis, bursitis, strains, sprains and acute gout. Remethan is also indicated for the control of pain and inflammation in orthopaedic, dental and other minor surgery.

In children, Remethan is indicated for the treatment of Juvenile chronic arthritis.

Dosage

For enteric-coated tablets:

The recommended adult dose of Remethan is 75-150mg daily given in two or three divided doses.

Children should be given 1,3mg/kg per day in divided doses.

For elderly patients the standard adult dose may be used.

For sustained release tablets:

Remethan Retard: One tablet daily, taken whole with liquid, preferably at meal times. If necessary, the daily dosage can be increased to 150mg by supplementation with conventional Remethan tablets. For milder cases, where a lower dosage is sufficient other dosage forms of Remethan may be used.

For Suppositories:

The recommended adult dose is one 100mg suppository daily, usually administered at night. In more severe cases, combined therapy with 25 or 50mg tablets is recommended. The total daily dose should not exceed 150mg.

Side-effects

Remethan is relatively free from serious side-effects. The side-effects are often transient and disappear with continuation of medication. These may include epigastric pain, nausea, diarrhoea, headache, slight dizziness, skin rashes, peripheral oedema and abnormalities of serum transaminases. Very rarely peptic ulcer and haematemesis or melaena have been reported. In such cases Remethan should be withdrawn.

Dermatological:

Occasional rashes or skin eruptions.

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Cases of hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome) and photo-sensitivity reactions have been reported.
Suppository: Local reactions include itching, burning and increased frequency of bowel movement.

Precautions

Remethan should be given with caution to patients with a history of peptic ulcer, haematemesis or melaena, or bleeding diathesis or with severe hepatic or renal insufficiency.
Pregnancy:
Remethan should not be prescribed during pregnancy, unless there are compelling reasons for doing so.
Drug Interactions:
Remethan may cause increased blood concentrations of Digoxin and Lithium. Although studies have demonstrated a pharmacokinetic interaction between Remethan and Salicylates it has been stated that this has no clinical significance. It has also been reported that Remethan, unlike some other non-steroidal anti-inflammatory agents, does not potentiate the effects of oral anticoagulants or hypoglycaemics. The natriuretic effects of Frusemide type diuretics have been reported to be inhibited by some non-steroidal anti-inflammatory drugs.
Methotrexate excretion is inhibited by non-steroidal anti-inflammatory drugs. Simultaneous administration of Methotrexate and non-steroidal anti-inflammatory drugs should probably be avoided. Occasional fatalities from renal failure have been reported. Severe cutaneous reactions, including Stevens-Johnson Syndrome and toxic epidermal necrolysis (Lyell's syndrome) have been reported with Diclofenac Sodium. Patients treated with Diclofenac Sodium should be closely monitored for signs of hypersensitivity reactions. Discontinue Diclofenac Sodium immediately if rash occurs.

Contra-indications

Remethan is contra-indicated in patients with peptic ulcer, previous sensitivity to Remethan and during pregnancy.

Overdosage

Management of a non-steroidal anti-inflammatory drug intoxication is primarily supportive and symptomatic. Fluid therapy is commonly effective in managing the hypotension that may occur following acute NSAID overdosage, except when this is due to an acute blood loss. The therapeutic measures to be taken are: absorption should be prevented as soon as possible after overdosage by means of gastric lavage and treatment with activated charcoal.

Pharmaceutical Precautions

Storage Conditions:
Remethan should be stored below 25°C, protected from light and moisture.
Incompatibilities:
None.
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