

Package leaflet: Information for the patient

Remethan 25 mg gastro-resistant tablets

Diclofenac sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Remethan
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1. What Remethan is and what it is used for

Diclofenac sodium, the active substance of Remethan, is a Non-steroidal Anti-inflammatory Drug (NSAID), belonging to the group of phenylacetic acid.

NSAID's are drugs used for the relief from the symptoms caused by arthritis (rheumatism), such as inflammation, oedema (swelling), rigidity and pain in the arthroses (joints). The action of the NSAID's is due mainly to the inhibition of the composition of prostaglandins. These drugs do not cure arthritis. They only help for as long as they are taken.

Remethan is used in painful conditions of the joints and the muscles.

It is indicated in rheumatoid arthritis, ankylosing spondylitis, tendinitis (inflammation of one tendon), synovial tendinitis (inflammation of the sheath of a tendon), bursitis (inflammation of one sheath), sprains, and in acute uric arthritis (gout).

Remethan is also indicated in treating pain and inflammation in surgery (orthopedic, dental and other operations). In children, Remethan is indicated in juvenile chronic arthritis.

2. What you need to know before you take Remethan

Do not take Remethan

- if you have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages. Do not take Remethan if you have

heart failure.

- if you have or have had problems with your blood circulation (peripheral arterial disease).
- if you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of this medicine (listed in section 6). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- if you have history of gastrointestinal bleeding or perforation related to previous NSAIDs therapy.
- if you have history or active peptic ulcer / haemorrhage.

Warnings and precautions

Talk to your doctor or pharmacist before taking Remethan.

- if you smoke.
- if you have diabetes.
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- if you are allergic to diclofenac, to any of the excipients of the product or to any other NSAID.
- if you are pregnant or you intend to become pregnant or if you are breast feeding.
- if you suffer from peptic or duodenal ulcer, asthma, and renal, cardiac or hepatic disease.
- if you suffer from intestinal disorders as for example ulcerous colitis, Crohn's disease.
- if you have bleeding diathesis or other problems related to blood.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Remethan, as Remethan can sometimes worsen wound healing in your gut after surgery.

Medicines such as Remethan may be associated with a small increase of the risk for cardiac attack («myocardial infarction») or cerebrovascular episode. This is more possible to happen when taking high doses and during prolonged therapy. Do not exceed the recommended dose or duration of treatment.

If you have cardiac problems, history of cerebrovascular episode or if you believe that you have an increased risk for such situations (for example if you have high pressure, diabetes, high cholesterol or if you are a smoker) you should discuss your therapy with your doctor or pharmacist.

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime, with or without warning symptoms or a previous history of serious GI events.

Remethan should be administered with caution to patients with a history of gastric or intestinal ulcer or other gastrointestinal disorders (ulcerative colitis, Crohn's disease), cardiac, renal or hepatic problems and to elderly people. The previously mentioned categories of patients are more susceptible to undesirable effects and so they should commence treatment on the lowest dose available.

In case of patients with gastrointestinal bleeding or peptic ulcer or perforation, the concomitant administration of diclofenac with protective agents (like misoprostol or proton pump inhibitors) is recommended. Protective agents should also administered in patients requiring concomitant low dose aspirin or other drugs likely to increase gastrointestinal risk.

Avoid concomitant administration of diclofenac with NSAIDs including cyclooxygenase-2-selective inhibitors.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Other medicines and Remethan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

As a number of medicines interact with NSAID's they should not be used concomitantly. However, a few of them can be used concomitantly under special precautions. In this case, your doctor can change the posology or take other cautions if needed. If you are to take a NSAID drug, it is important to inform your doctor or pharmacist if you are taking any other medications and particularly any of the following:

Anti-coagulants (warfarin), anti-platelet agents, selective serotonin reuptake inhibitors, antidiabetic agents, cyclosporin, methotrexate, quinolone antimicrobials, other NSAIDs, corticosteroids, diuretics, cardiac glycosides, mifepristone, anti-hypertensives, lithium, digoxine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Since the safe use of NSAID's during pregnancy has not been clarified, their use should be avoided. Consult your doctor or pharmacist before taking any medication.

Diclofenac is excreted into human milk and therefore it is not recommended during lactation. Consult your doctor or pharmacist before taking any medication.

Do not take Remethan if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Remethan during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Remethan can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Driving and using machines

Remethan causes dizziness and therefore, it may affect the ability to drive or operate machinery.

Excipients warnings

Remethan contain lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Remethan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Please follow your doctor's instructions.

Adults

The usual dose for adults is 25-50 mg 2 to 3 times daily. Maximum daily dose 150 mg.

Children

1-3 mg/kg/24 hours, in divided doses .

Elderly

Remethan should be used with caution in elderly people, who are generally more susceptible to its undesirable effects. It is particularly recommended that use should be made of the lowest effective dosage for adults.

If you take more Remethan than you should

In case of overdose contact your doctor immediately.

Overdosage symptoms: Irritation of the stomach and intestines, hypotension, convulsions, respiratory disorders, renal failure.

Treatment is symptomatic and supportive. It is recommended to have a gastric lavage and treatment with active charcoal as soon as possible, in order to avoid absorption of the medicine.

If you forget to take Remethan

If you must take the medicine continuously and you missed a dose, take the missed dose as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious. Stop using Remethan and tell your doctor straight away if you notice:

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Remethan and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Other undesirable effects that have been observed with Remethan are: peptic ulcer, perforation, gastrointestinal bleeding (haematemesis, melaena, bloody diarrhea)-sometimes fatal especially in elderly, epigastric pain, nausea, vomiting, diarrhea, abdominal cramps, dyspepsia, flatulence, anorexia, gastro-intestinal ulcer with or without bleeding or perforation, aphthous stomatitis, glossitis, oesophageal lesions, lower gut disorders (haemorrhagic colitis, exacerbation of ulcerative colitis or Crohn's proctocolitis, colonic damage), pancreatitis, constipation, gastritis, headache, dizziness, vertigo, drowsiness, tiredness, disturbances of sensation, paraesthesia, memory disturbances, disorientation, insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reactions, aseptic meningitis, disturbances of vision (blurred vision, diplopia), impaired hearing, tinnitus, taste disturbances, rashes, urticaria, bullous eruptions, eczema, erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome (acute toxic epidermolysis), erythroderma (exfoliative dermatitis), loss of hair, photosensitivity reactions, purpura including allergic purpura, oedema, acute renal insufficiency, urinary abnormalities (haematuria, proteinuria), interstitial nephritis, nephritic syndrome, papillary necrosis, elevation of hepatic enzymes (AST, ALT), liver function disorders (hepatitis with or without jaundice), thrombocytopenia, leucopenia, agranulocytosis, aplastic or haemolytic anaemia, hypersensitivity reactions (bronchospasm, anaphylactic/anaphylactoid systemic reactions including hypotension, vasculitis, pneumonitis, palpitations, chest pain, hypertension, congestive heart failure, impotence.

Medicines such as Remethan may be associated with a small increase of the risk for cardiac attack («myocardial infarction») or cerebrovascular episode.

If you have adverse reactions that are not mentioned above, please inform your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Malta

ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal

5. How to store Remethan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label or carton after 'EXP'. The expiry date refers to the last day of that month.

Store below 25 °C. Protect from light and moisture.

6. Contents of the pack and other information

- The active ingredient is diclofenac sodium. Each gastro-resistant tablet contains 25 mg diclofenac sodium.
- The other ingredients are: povidone, lactose, maize starch, microcrystalline cellulose, pregelatinised starch, colloidal silicon dioxide, magnesium stearate, talc, polyethylene glycol 6000, titanium dioxide E171, yellow ferric oxide E172, polysorbate 80, simeticone, methacrylic acid copolymer.
See paragraph 2 'Excipients warnings'.

What Remethan looks like and contents of the pack

Yellow, round, gastro-resistant tablets.

Pack sizes:

PVC/Aluminium blisters. Pack sizes of 30 and 1000 gastro-resistant tablets.

PP containers with PE closure. Pack size of 1000 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Remedica Ltd

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For internal use only: mt-pl-remethan-25mg-ec-tabs-a5