PATIENT INFORMATION

Tratul® retard 100 mg tablets

Reg.No.: 1-18204

Marketing authorization holder and manufacturer:
Gerot Pharmazeutika Vienna

Composition:
1 film-coated tablet (prolonged release) contains:
Diclofenac sodium 100 mg

Characteristics and Action:
The active substance contained in Tratul retard 100 mg tablets shows good efficacy against inflammations, pain and fever; due to the special pharmaceutical preparation, it is set free only in the small intestine where it is slowly released.
Due to the delayed release of the active substance, its action persists over a longer period so that once daily administration of a Tratul retard 100 mg tablet is usually sufficient.

Indications:
Treatment of painful inflammatory reactions and swelling associated with rheumatic diseases affecting joints (including the vertebral region), various forms of soft-tissue rheumatism (for instance shoulder-arm syndrome), painful swelling and inflammations e.g. after surgery (tooth extractions) or injuries and in gynaecology.

Method of administration:
To be swallowed before or during a meal with some liquid.
The film-coated tablets must not be divided or chewed.

Dosage:
Follow the dosing instructions exactly unless prescribed otherwise.
Tratul retard tablets are especially suited for patients whose symptoms require treatment with a daily dose of 100 mg.
Adults and adolescents over 12 years of age:
In general, 1 film-coated tablet once daily. If necessary, your doctor may tell you to take one 50 mg Tratul capsule or one 30 mg or 60 mg Tratul suppository (corresponding to 25 mg and 50 mg diclofenac, respectively) in addition to the tablet; however, a total daily dose of 150 mg diclofenac must not be exceeded.

Contraindications:
Tratul must not be used in the following cases:
Hypersensitivity to diclofenac. Patients who have reacted to certain drugs against pain or rheumatism (e.g. acetylsalicylic acid) with asthma attacks, allergic rhinitis or skin eruptions. Ulcers in the stomach or intestine; porphyria (a rare blood disorder), haemorrhagic diathesis (tendency to bleed more easily), disturbed blood formation (this may show as ulcers in the throat, extreme paleness and tiredness).

In the following cases your doctor will carefully consider whether Tratul may be used:
severely disturbed function of the liver, kidneys or heart;

severe hypertension, history of gastrointestinal bleeding or ulcers, chronic inflammation of the bowels, patients suffering from asthma, hay fever or chronic respiratory diseases.

Pregnancy and lactation period:
Tratul must not be used during the last 3 months of pregnancy.
During the first 6 months of pregnancy and during lactation, Tratul is to be used only when expressly prescribed by your doctor.

Side effects:
Side effects are seen only rarely and usually disappear rapidly after the end of treatment:
gastrointestinal complaints, such as nausea, abdominal pain, diarrhoea, eructation; reddening of the skin - rash, itching, headache, dizziness, drowsiness, swelling due to oedema, especially in the limbs.
In rare cases bleeding and – even more rarely – formation of ulcers in the gastrointestinal region (symptoms include paleness, tiredness and bloody or black stools), in exceptional cases also perforation (severe abdominal pain, abdominal tension), hypersensitivity reactions, e.g. in the form of marked respiratory distress, impaired kidney function (acute renal failure) or liver function (yellowing of the skin), blood changes and drop in blood pressure.

Occasionally other side-effects have been reported, such as sleep disturbances, agitated states, irritability, transient hair loss, severe changes on the part of the skin or mucosae, inflammation of the eyes, disturbed vision, spasms, sensory disturbances as well as severe bone marrow damage.
Medicines such as Tratul may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

Interactions:
If you are using any other drugs beside Tratul, you must inform your doctor because diclofenac may either increase or reduce the effect of other medicines.
Use of Tratul increases.
– the effect of lithium, digoxin, possibly also of potassium-sparing diuretics
– the risk of gastrointestinal bleeding if administered together with glucocorticoids
– the side effects of other antirheumatics and of methotrexate
– the effect of drugs inhibiting platelet aggregation (e.g. dipyridamole, sulfinpyrazone)

If used together with acetylsalicylic acid, the concentration of Tratul in the blood may be decreased.

Use of Tratul decreases
the effect of furosemide and similar diuretics and of antihypertensive substances. If medicines lowering blood sugar (oral antidiabetics) or inhibiting blood coagulation (e.g. coumarin derivatives, heparin) are used together with Tratul, usually no interactions are expected.

Habituation:
None known.

Special Precautions for Safe Use:
Please report any symptoms of side effects to your doctor.
In case of severe pain in the abdominal region, black or bloody stools, skin eruptions with inflammation of the mucosa and/or the eye, discontinue Tratul immediately and consult your doctor.

Medicines such as Tratul may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Inform your doctor if you become pregnant.

You must follow your doctor's instructions with regard to laboratory tests.

⚠ Caution: Use of this drug may affect the patient's reactivity and ability to drive. If dizziness or tiredness are observed, the patient should be warned to exercise caution when driving or operating machinery.

Massive overdose may result in a potentiation of side effects on the part of the gastrointestinal tract or the nervous system (e.g. increased agitation). Please consult your doctor immediately.

Do not use after the expiry date!
Keep out of reach of children!

Package sizes:
30 and 50 tablets.

Special precautions for storage:
Do not store above 25°C. Protect from light.

Consult your doctor or pharmacist if you are in any doubt.

Gerot Pharmazeutika Vienna, Austria