Tratul®50 mg capsules

antirheumatic, antipyretic, anti-inflammatory, analgesic

Composition
diclofenac 50 mg

Characteristics
The non-steroidal active substance diclofenac exerts an antirheumatic, antiphlogistic, analgesic as well as antipyretic effect mainly by means of an inhibition of prostaglandin synthesis; administered in high dosages it transitorily inhibits experimentally induced platelet aggregation.
Tratul capsules are enteric-coated. Consequently diclofenac acid is well absorbed by the alkaline environment of the small intestine and is well tolerated even during long-term therapy.
In healthy volunteers, peak plasma values were observed 2 hours after the intake of 2 capsules.
protein binding: 99,7%
Approximately 60% of the administered dose are excreted via the kidneys in form of pharmacologically active metabolites and less than 1% as unchanged active substance. About 30% of the dose are excreted in metabolite form with the faeces. As biliary excretion is enhanced, cumulation of the active substance does not occur with cases of renal insufficiency. Absorption, metabolism and excretion are independent of the patient's age.

Indications
1. Tratul is particularly indicated in the treatment of painful inflammatory reactions due to acute and chronic rheumatic processes such as:
   arthritis and polyarthritis of various etiology, lumbalgia in intervertebral arthrosis, primary chronic polyarthritis, extraarticular (soft-tissue) rheumatism (e. g. bursitis, tendovaginitis, myalgias due to myositis or myogelosis, periarthritis humeroscapularis, etc.)
2. as well as for the treatment of:
   chronic degenerative or deforming affections of the locomotor system (spondylosis, arthrosis, ankylosing spondylitis = M. Bechterew) and acute attacks of gout.
3. Posttraumatic swellings and inflammations (due, e.g. to sports injuries, minor surgical interventions or tooth extractions).
4. Dysmenorrhea.

Administration
To be taken before meals with some liquid. The capsules are neither to be broken into bits nor to be chewed.

Dosage
Dosages are to be determined according to the individual clinical picture.

adults and children over 12 years of age:
Generally 1 capsule 2 to 3 times a day.
A total daily dose of 150 mg diclofenac should not be exceeded.

elderly patients:
In spite of the fact that the pharmacokinetics are independent of the patient's age, dosages for elderly patients should be determined with particular care.

Contraindications
- Ulcus ventriculi et duodeni.
- Hypersensitivity to diclofenac.
- Patients who suffered from asthma attacks, urticaria or acute rhinitis after the intake of acetyl-salicylic acid or other medications inhibiting prostaglandin synthetase.
- Porphyria, hemorrhagic diathesis, disturbances of hematopoiesis.

Caution is to be exercised in patients suffering from asthma, hay fever or chronic diseases of the respiratory tract as well as severe renal, cardiac, hepatic diseases, severe hypertension, Morbus Crohn, colitis ulcerosa or anamnestic gastrointestinal ulcera.

Pregnancy and Lactation
During the first 6 months of pregnancy therapy is only indicated when absolutely necessary and with the lowest effective doses. During the last 3 months of pregnancy diclofenac is not to be administered at all (possibility of inhibition of uterine contractions and premature closure of the Botallo's duct!).
If definitely necessary, treatment of nursing mothers may be tolerated as only very small amounts of the active substance pass into the mother's milk after oral administration of 150 mg diclofenac daily. There are no observations concerning the effects on the new-born.

Side-Effects
Being generally well tolerated, Tratul may nevertheless cause the following side-effects:
- gastrointestinal disturbances (e.g. epigastric pain, nausea, diarrhea, eructation, occult bleedings)
- cephalea, vertigo, drowsiness
- ekcema, rush, pruritus
- fluid retention, peripheral edemas

rarely:
- gastrointestinal ulcera accompanied by severe bleedings and causing perforation (anemia), unspecific hemorrhagic colitis, exacerbation of a pre-existing colitis ulcerosa
- insomnia, states of excitation, irritation
- allergic reactions like bronchial spasms, anaphylactic/anaphylactoid reactions; hypersensitivity reactions.
- renal insufficiency, nephrotic syndrome, acute renal failure, hematuria
- hepatitis (jaundice, increase of transaminases)
- disturbances of hematopoiesis (leukopenia, thrombopenia, aplastic anemia, panmyelopathy)
- hypotension

isolated cases of:
- disturbances of sensibility, visual disturbances (blurred vision, diplopia), tinnitus, cramps
- reversible alopecia, Stevens-Johnson's syndrome, Lyell's syndrome, erythema exodativum multiforme, photosensitization
- interstitial nephritis, papillary necrosis
- purpura, agranulocytosis, hemolytic anemia

Drug Interactions
The concomitant administration of diclofenac and other pharmaceutical preparations may enhance or decrease the effect of the latter ones:

increase:
- of the plasma levels of lithium and digoxin
- of the risk of a gastrointestinal bleeding caused by a simultaneous therapy with glucocorticoids
- of the side-effects of other non-steroidal antirheumatics
- possibly of the effect of potassium sparing diuretics (controls of the potassium levels are recommended)
- of the effect of medications inhibiting platelet aggregation

The administration of non-steroidal antiphlogistics should be avoided for 24 hours prior to and after treatment with methotrexate, as this may cause an increase of methotrexate blood levels followed by an increase of the substance's toxicity.

decrease
- of furosemide and other diuretics acting via the loop of Henle
- of antihypertensives

A concurrent intake of acetyl-salicylic acid decreases the serum concentration of diclofenac and vice versa.
Clinical studies demonstrated that diclofenac influences neither the effect of oral antidiabetics nor the effect of anticoagulants. As a cautionary measure it is nevertheless recommended to control the anticoagulant effect by means of laboratory tests when administering diclofenac and anticoagulants concomitantly.

Cautionary Advice
During long-term therapy with diclofenac (more than 2 weeks) tests of the renal function especially but as well of hepatic function, blood count and coagulation should be carried out.
Renal functions are to be observed with special caution when immediately administering diclofenac postoperatively.
The preparation is to be discontinued whenever peptic ulcera develop or gastrointestinal bleedings occur during the treatment, cases which were only rarely observed.

Information for the Patient
Your physician is to be informed of the first symptoms of side-effects.
The intake of Tratul is to be discontinued and the physician to be consulted immediately after the occurrence of severe pain in the abdominal area, black or hemorrhagic stool, cutaneous eruptions accompanied by inflammation of the mucosa or the eyes.
The physician is to be informed of pregnancy.
If you are concurrently applying any other medication besides Tratul, you should talk to your physician, as the effect of other medications may either be enhanced or decreased by Tratul.
On the occurrence of vertigo or fatigue, special caution is to be exercised while driving or handling machines.

Overdosage
Severe manifestation of side-effects in the gastrointestinal area and in the CNS. Therapy is to be chosen according to symptoms.

Pack Size
30 capsules

Storage Advice
Store at room temperature not exceeding 25° C. Protect from light.
Keep out of the reach of children!

Sole Agent in Lebanon and Syria
LIBA PHARM

Ex 307630298

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