

DOLOSTAN®

500 mg, Coated Tablets

Antipyretic, non-steroidal anti-inflammatory, analgesic, antirheumatic

COMPOSITION

Each coated tablet for oral administration of DOLOSTAN tablet contains 500 mg of mefenamic acid.

Excipients: lactose monohydrate, croscarmellose sodium, povidone K, Avicel pH 102, talc, magnesium stearate, colloidal silicon anhydrous

INDICATIONS

DOLOSTAN is indicated in:

- 1-Rheumatic diseases and pains: Muscular pain, joint inflammation, inflammation of the tendon, pain in the vertebral column (affecting the shoulders, the nape of the neck, the intervertebral discs); osteoarthritis;
- 2-ORL affections: otalgia, otitis, influenza diseases; upper respiratory tract affections: sinusitis, amygdalitis, pharyngitis, laryngitis, as well as bronchitis and pneumonia;
- 3-Fever-associated illnesses, notably in the upper respiratory tract
- 4-Pains following surgical and dentosurgical interventions (dental extractions and odontalgia) and pains due to traumas and migraine;
- 4-In case of painful periods or heavy bleeding.

CONTRAINDICATIONS

DOLOSTAN is contra-indicated for patients with gastrointestinal ulcer or with tendency towards heavy bleeding as well as with an established hypersensitivity (asthma, urticaria, fever) to other analgesics (such as acetylsalicylic acid). When hypersensitivity to mefenamic acid is observed in form of diarrhea, vomiting, cephalalgia, dizziness, fatigue, visual troubles and skin rash, DOLOSTAN should not be administered.

ADVERSE REACTIONS

Following the administration of high doses during a prolonged period, cases of diarrhea may occur. If such cases continue to occur, The DOLOSTAN treatment should be stopped. Symptoms such as gastralgia, nausea and vomiting have been observed in certain patients with highly sensitive stomachs. In such rare cases, central effects such as cephalalgia, dizziness, fatigue or visual troubles, skin rash or swelling of the ankles have been observed.

In rare cases, hepatic and renal dysfunctions as well as changes in the blood count have been established. If you should take DOLOSTAN for a prolonged period, you should undergo medical examinations regularly as ordered by your physician.

In case of hypersensitivity to an active component, namely the mefenamic acid, allergic reactions may occur. In this case, the medication should be suspended immediately and the physician should be informed without delay.

If, during treatment, symptoms such as throat pain (tonsillitis), high fever and eventually swelling of the lymphatic glands in the neck region (very rare syndrome), as well as epigastric pain and/or black colored stools, the medication should be suspended immediately and the physician should be informed without delay.

PREGNANCY AND LACTATION

During pregnancy or breastfeeding period, the medication may only be used upon your physician's prescription. DOLOSTAN should not be taken during the last three months of pregnancy.

PRECAUTIONS

This medication may affect one's reactions, ability to drive and ability to use tools or machines.

Specific precautions are indicated regarding the use of DOLOSTAN in the presence of severe heart, hepatic and renal diseases as well as in cases of hypertonicity and epilepsy. Inform your physician or pharmacist if you suffer from another disease, if you are allergic or if you are already on other medications.

DOSAGE AND ADMINISTRATION

Dosage should be estimated individually by the physician, according to age and etiology of the disease. Consequently, it is generally essential to follow the indicated dosages. Adults and children 14 years of age and older: 1 coated tablet of 500 mg 3 times per day during meals to a maximum of 4 coated tablets per day

DOLOSTAN coated tablets are swollen without chewing with the meals.

CONSERVATION

Keep out of reach of children
Store at room temperature (15-25°C).
Do not use after the expiry date stated on the box after "EXP"

PRESENTATION

DOLOSTAN, mefenamic acid 500 mg, pack of 20 coated tablets.

Revision date: 10/2009
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