Diclon 12.5 mg, 25 mg, 50 mg, 100 mg

Pharmaceutical form: Rectal suppositories.

Composition: Each suppository contains diclofenac sodium 12.5 mg, 25 mg, 50 mg, 100 mg and hard fat.

Pharmacodynamics:

Diclon rectal suppositories contain diclofenac sodium - non-steroidal anti-inflammatory drugs (NSAIDs) with pronounced antirheumatic, anti-inflammatory, analgesic and antipyretic action. It inhibits the synthesis of prostaglandins, which have an important role in the formation of inflammation, pain and fever.

Pharmacokinetics:

Diclofenac is rapidly absorbed from the gastrointestinal tract. The maximum plasma concentration is attained in less than 1 hour after the use of suppositories. It is metabolized and excreted mainly in the urine. A small amount is also excreted in the bile.

Indications

Adults

Relief of pain of various degrees and inflammation in a wide range of pathological conditions, including:

- inflammatory and degenerative diseases of the musculoskeletal system: rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute attack of gout.
- Acute disorders of the musculoskeletal system such as periarthritis (eg, frozen shoulder syndrome), tendinitis, tenosynovitis, bursitis.
- Post-traumatic and postoperative pain syndromes in dental and orthopedic practice.

Children from 1 to 12 years

Juvenile rheumatoid arthritis (suppositories 12.5 mg and 25 mg).

Children aged 6 and over years

As monotherapy or as an adjuvant with morphine or other opiates for the relief of postoperative diseases (12.5 mg and 25 mg suppositories).

Dosage and administration:

Suppositories should be inserted into the rectum as deeply as possible, preferably after bowel movement. Suppositories should not be divided into parts, since such a change in the way the drug is used can lead to a violation of the distribution of the active substance.

Adults

The recommended internal dose - 75 – 150 mg/daily in multiple introductions (25 mg, 50 mg and 100 mg). In milder cases of diseases, as well as for long-term therapy 75 -100 mg/daily is usually sufficient. The total daily dose should generally be divided into 2 to 3 separate doses. To suppress nocturnal pain and morning stiffness, treatment with tablets during the day can be supplemented by the administration of a suppository at bedtime up to a total maximum daily dose of 150 mg.

Children from 1 to 12 years

The drug is prescribed at the rate 0.5 to 2 mg/kg body weight/daily divided into 2 to 3 separate doses.

For treatment of acute postoperative pain syndromes must be limited to 4 days (suppositories 12.5 mg and 25 mg).

For treatment of juvenile rheumatoid arthritis, the dose can be raised up to a maximum of 3 mg/kg body weight/daily, dose is divided into 2 to 3 separate doses (suppositories 12.5 mg and 25 mg).

Elderly

Although the pharmacokinetics of Diclon does not lead to any clinically relevant extent in elderly patients, non-steroidal anti-inflammatory drugs must be used with particular caution in such patients who generally are more prone to adverse reactions. In particular, it is recommended to use the lowest effective dose for elderly or patients with low body weight, and it is also necessary to control gastrointestinal bleeding within 4 weeks from the start of NSAIDs.

Adverse reactions:

From the side of gastrointestinal system: nausea, vomiting, anorexia, pain and discomfort in the epigastric region, flatulence, constipation, diarrhea; in some cases - erosive and ulcerative lesions, bleeding and perforation of the gastrointestinal tract; rarely - liver dysfunction. With rectal administration, in individual cases, inflammation of the colon with bleeding, exacerbation of ulcerative colitis were noted.

From the side of the central nervous system and peripheral nervous system: dizziness, headache, agitation, insomnia, irritability, feeling tired; rarely - paresthesia, visual impairment (blurring, diplopia), tinnitus, sleep disorders, convulsions, irritability, tremor, mental disorders, depression.

On the side of the hematopoietic system: rarely - anemia, leukopenia, thrombocytopenia, agranulocytosis.

From the urinary system: rarely - impaired renal function; edema may occur in predisposed patients.

Dermatological reactions: rarely, serious skin reactions.

Allergic reactions: skin rash, itching;

Local reactions: with rectal administration, local irritation, the appearance of mucous secretions mixed with blood, and painful defecation are possible.

Contraindications:

- gastric and duodenal ulcers in the acute stage,
- hypersensitivity to the diclofenac or to any of the excipients,

- information in anamnesis about attacks of bronchial asthma, urticaria, acute rhinitis associated with the use of acetylsalicylic acid or other NSAIDs, as well as any drugs that suppress the production of prostaglandins,
- proctitis,
- severe liver, kidney, or heart diseases,
- history about gastrointestinal bleeding and perforation associated with previous NSAID therapy,
- information in anamnesis about recurrent peptic ulcer (two or more distinct episodes of proven ulceration or bleeding),
- III trimester of pregnancy.

Warnings and precautions:

close medical surveillance is imperative and particular caution should be exercised when prescribing diclofenac in patients with symptoms indicative of gastrointestinal (GI) disorders or with a history suggestive of gastric or intestinal ulceration, those with ulcerative colitis or Crohn's disease, or those with liver dysfunction, bleeding/perforation of GI tract.

Caution should be exercised when using diclofenac in elderly patients.

With anamnesis of allergic reactions to NSAIDs and sulfites, diclofenac is used only in urgent cases. In the process of treatment, systematic monitoring of liver and kidney function, peripheral blood patterns is necessary.

Rectal use is not recommended in patients with anorectal disease or with anamnesis of anorectal bleeding.

During the period of treatment with pharmaceutical forms of systemic use, alcohol is not recommended.

Impact on the ability to operate a motor vehicle safely

During the period of treatment, a decrease in the rate of psychomotor reactions is possible.

Pregnancy and period of breastfeeding:

Pregnancy

Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or embryonic/fetal development.

Some epidemiological studies suggest an increased risk of miscarriage and/or cardiac malformations and gastroschisis after use of a prostaglandin synthesis inhibitor (such as NSAIDs) in early pregnancy, however the overall data are inconclusive. The absolute risk of cardiovascular malformations increased from less than 1% to approximately 1.5%. It is believed that the risk increases with increasing dose and duration of treatment. In animals, the use of a prostaglandin synthesis inhibitor resulted in an increase in the number of pre- and post-implantation losses and embryo/fetal mortality. In addition, in animals treated with a prostaglandin synthesis inhibitor during organogenesis, there was an increased frequency of various malformations, including those of the cardiovascular system. If Diclon is used in women who are

attempting to conceive or in the first trimester of pregnancy, the dose of the drug should be as low as possible and the duration of treatment as short as possible.

During the third trimester of pregnancy all prostaglandin synthesis inhibitors may have the following effects on the fetus:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension)
- impaired intrauterine development of the kidneys with the subsequent development of impaired kidney function, which can progress to kidney failure with oligohydramnios.

Regarding the mother at the end of pregnancy and the newborn:

- possible prolongation of bleeding time, antiplatelet effect that may occur even at very low doses,
- inhibition of uterine contractions, which leads to a delay or increase in the duration of labor. Thus, the drug Diclon is contraindicated in the third trimester of pregnancy.

Breastfeeding

Like other NSAID, diclofenac passes into the breast milk in small amounts. Therefore, suppositories of drug of Diclon should not be administered during breastfeeding in order to avoid undesirable effects in the
infant.

Fertility

As with other NSAIDs, Diclon may impair female fertility that is why is not recommended to prescribe the drug in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Diclon should be considered.

Packaging:

10 suppositories in pack 12.5 mg, 25 mg, 50 mg, 100 mg.

Shelf life:

3 years

Storage conditions:

Store below 25 ºC.

Keep out of reach of children.

Regulatory status:

Prescription only.