FENADOL

DICLOFENAC

Modified-release tablets - Suppositories

COMPOSITION:
Each 100 mg modified-release tablet contains: Active ingredient: Diclofenac sodium 100 mg. Excipients: Microgranular cellulose, Lactose, Starch, Polyvinylpyrrholidon, Magnesium stearate, Hydroxypropylcellulose, Diethylphtalate, Cellulose acetophthalate, Titanium dioxide.
Each 100 mg suppository contains: Active ingredient: Diclofenac sodium 100 mg. Excipients: Solid semi- synthetic glyceride.

PHARMACEUTICAL FORM – PACKAGING
20 modified-release tablets 100 mg - 10 suppositories 100 mg

PHARMACO-THERAPEUTICAL CLASS
Non-steroidal anti-inflammatory product.

MARKETING AUTHORISATION HOLDER
PROGE FARM S.r.l. - Baluardo La Marmora, 4 - 28100 NOVARA

MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE
Modified-release tablets: Omicron Pharma S.r.l., Via Follereau 25, 24027 Nembro (BG) - Italy
Suppositories: Fulton Medicinali S.p.A., Via Marconi 28/9, Arese (MI) - Italy

THERAPEUTIC INDICATIONS
Inflammatory and degenerative rheumatic affections like: rheumatoid arthritis and ankylosing spondylitis; arthrosis; extra-articular rheumatism. Pain caused by extra – rheumatic or post-traumatic inflammation. Symptomatic treatment of primary dysmenorrhea (menstrual pain).

CONTRAINDICATIONS
Hypersensitivity to components or chemically-related substances.
This product should not be used in case of gastric or duodenal ulcer, serious gastroenteric disorders, serious kidney and/or hepatic insufficiency, during pregnancy and nursing, during intense therapy with diuretics, in patients with ongoing haemorrhage and haemorrhagic disposition, in case of haemopoiesis alterations and concomitant treatment with anticoagulants since a synergetic action may occur.
Diclofenac, like other non-steroidal anti-inflammatory substances, is contraindicated in patients showing urticaria or acute rhinitis after intake of acetylsalicylic acid or other drugs which inhibit the prostaglandin-synthetase.
Suppositories must not be administered to patients with haemorrhoids or who have recently suffered from proctitis.
The medicinal product is contraindicated in children up to 14 years, during pregnancy and nursing.

PRECAUTIONS FOR USE
Do not use FENADOL in case of renal hypoperfusion, heart or kidney failure, arterial hypertension, thrombo-embolic phenomena recorded during the clinical history of the patient, patients being treated with diuretics or who have just undergone major surgery, elderly patients.
During long-term treatment with FENADOL or other non-steroidal highly-active anti-inflammatory substances, blood crasis and hepatic and renal functionality checks are recommended as precautionary measures.
The minimum efficient dose is recommended for elderly and less-than-average-weight patients.

Because of the presence of benzyl alcohol, FENADOL must not be given to children under 2 years of age.
Because of the presence of 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.
The product is not recommended for patients under 14 years of age.

INTERACTIONS

If administered together with preparations containing digoxin, Diclofenac may increase its plasmatic concentration, but in these cases no clinical overdosage signs have been reported.
The simultaneous administration of lithium salts is not recommended as it may increase the lithiemia.
Many non-steroidal anti-inflammatory drugs may inhibit the activity of diuretic and strengthen the effect of potassium-sparing diuretics; then the control of the potassium serum level is necessary.
The contemporary administration of non-steroidal anti-inflammatory products may increase the frequency of side effects.
NSAIDs drugs can increase the effects of anticoagulant products like warfarin. Isolated cases of increased risk of haemorrhage were observed as a result of combined use of Diclofenac sodium and anticoagulant therapy. These patients should be closely monitored. High doses of Diclofenac, like other NSAIDs, may temporarily inhibit the platelet aggregation.
The administration of non-steroidal anti-inflammatory substances less than 24 hours before or after treatment with methotrexate should be carefully monitored, because such drugs may increase its haematic concentration and toxicity.
Even if widely bound to proteins, it does not interfere with the proteic bond of salicylates, tolbutamide, prednisolone.
It does not increase the hypoglycaemic effect of tolbutamide, biguanides, glibenclamide.
It does not influence negatively the glucose metabolism in diabetic patients and healthy subjects.
FENADOL may increase the nephrotoxicity of cyclosporin through its inhibiting effect on renal prostaglandines.

WARNINGS

Accurate diagnosis and strict medical monitoring are needed in patients with symptoms of gastroenteric disorders, whit a history that may indicate gastrointestinal ulcer, with ulcerative colitis or with Crohn’s disease and in patients suffering from serious hepatic insufficiency. The treatment must be interrupted when peptic ulcer or gastroenteric haemorrhage occur.
When the parameters of hepatic functionality are persistently altered or become worse, the treatment with FENADOL must be interrupted. Particular care is needed in patients suffering from hepatic porphyria, a disorder caused by abnormalities in the chemical steps leading to the production of heme, a substance that is important in the body. The product may cause bronchial spasms, shocks and other allergic phenomena in sensitive subjects or asthmatic patients.
Do not use the product during pregnancy and nursing and in patients under 14 years of age.
Patients feeling dizzy or showing other central nervous system disorders should not drive the car or any other vehicle needing alertness.

Keep this product out of the reach of children.

POSOLOGY AND METHOD OF ADMINISTRATION

Modified- release tablets: one tablet daily. If the symptoms are more marked during the night or in the morning, FENADOL should be preferably taken in the evening. The tablets must be swallowed whole with water, preferably during the meals.
The use of the product is limited to adults.
In the treatment of aged patients the posology must be carefully established by the physician, who

will have to evaluate a possible reduction of the above mentioned doses.
Suppositories: suppositories are particularly indicated to eliminate or relieve the nightly pain and the morning rigidity. Posology is one suppository daily, given in the evening before to go to bed.
Administer only by rectal way.

OVERDOSE

Treatment of acute poisoning with non-steroidal anti-inflammatory substances includes support and symptomatic measures. So, in case of overdose, please refer to your doctor.

SIDE EFFECTS

Gastroenteric disorders like nausea, vomit, diarrhoea and flatulence may occur at the beginning of the therapy. Contact a physician in case of more serious problems like epigastric pain, evident or hidden gastroenteric haemorrhage (dark faeces). Peptic perforated ulcer and colon disorders have seldom been reported.
The following allergic reactions rarely appear: cutaneous rash, pruritus, oedema, asthmatic and /or anaphylactic fits, which may be accompanied by hypotension. Photosensitivity and serious cutaneous reactions, like erythema multiforme and bullous dermatosis (Stevens-Johnson syndrome, Lyell's syndrome), are exceptional events.
Central nervous system disorders like headache, tension, irritability, insomnia, lack of energy and strength, dizziness, convulsions, sensorial or vision disorders and tinnitus (ringing, swishing, or other type of noise that seems to originate in the ear or head) have seldom been reported.
Peripheral oedemas, renal failure, nephrotic syndrome, transaminase increase, jaundice, haematopoiesis disorders (lower than the normal amount of white blood cells, platelets and granulocytes, a type of white blood cell filled with microscopic granules; haemolytic anaemia), kidney diseases and loss of hair may occur, especially in long-term treatments.
Urinary disorders, interstitial nephritis (nephritis due to disorders of the connective tissue within the kidney, severe allergic reactions, exposure to toxic substances, transplant rejection, urinary blockage, or other factors), hepatic functionality disorders (such as hepatitis with or without jaundice, in rare cases fulminating) have been rarely recorded.
In some patients suppositories may cause local and temporary side effects.
Any side effects which are not herein described should be timely communicated to your physician or pharmacist .

SPECIAL STORAGE PRECAUTIONS

Modified-release tablets: store sheltered from humidity.
Suppositories: store sheltered from heat.

EXPIRY DATE

The expiry date on the box provided that the product is properly packed and stored.
DO NOT USE AFTER THIS DATE.

Approved on 17.03.1997