DOLMINA™ 50 mg

Film-coated tablets
Diclofenac sodium

ZENTIVA
A SANOFI COMPANY

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What DOLMINA™ 50 mg is and what it is used for

Dolmina™ 50 mg contains diclofenac as the active ingredient, which belongs to a group of drugs called a Non-Steroidal Anti-Inflammatory Drug (NSAID) and which suppresses the production of substances that contribute to the development of inflammation.

Dolmina™ 50 mg is a medicinal product which relieves inflammation and pain and also reduces fever accompanying inflammatory diseases. Dolmina™ 50 mg also reduces muscle stiffness and swelling of joints and thereby helps to improve their function. It has no effect on the cause of inflammation or fever.

Dolmina™ 50 mg is used by adults and by adolescents over 14 years of age for:
- inflammatory & degenerative diseases of the musculoskeletal system,
- pain after surgery or injury,
- back pain,
- relief of menstruation pain,
- in gynaecological inflammation,
- acute gout attack,
- painful infectious diseases of the ear, nose and throat.

2. Before you take Dolmina™ 50 mg

Do not take Dolmina™ 50 mg:
- if you are allergic to diclofenac or any of the other ingredients in this medicine (listed in section 6),
- if you are allergic to salicylates (e.g. acetylsalicylic acid) or to any anti-inflammatory drugs and in the past or at present you have developed reaction after taking these medicines, e.g. bronchial asthma or urticaria,
- if there is active bleeding, ulcer or perforation of the gastrointestinal tract,
- if there has been bleeding or perforation of the gastrointestinal tract caused by non-steroidal anti-inflammatory drugs in the past,
- if there has been repeated bleeding or stomach or duodenal ulceration in the past (two or more episodes).
- in severe heart failure,
- if you suffer from a severe kidney or liver function disorder,
- if you are in the third trimester of pregnancy (last three months).

The product is not intended for children and adolescents to 14 years of age.

Take special care with Dolmina™ 50 mg in the following cases:
- If you take Dolmina™ 50 mg together with other non-steroidal anti-inflammatory drugs such as acetylsalicylic acid, corticosteroids, anticoagulants (e.g. warfarin) or medication to treat depression (SSRI – selective serotonin reuptake inhibitors), see section "Other medicines and Dolmina™ 50 mg".
- If you suffer from asthma or hay fever (seasonal allergic rhinitis).
- If you ever suffered from gastrointestinal problems such as stomach or duodenal ulcers (if you had ulcers repeatedly, the product must not be used), bloody or black faeces, or if you had problems with digestion in the past or heart burn after previous use of anti-inflammatory drugs.
- If you suffer from inflammatory bowel disease, such as e.g. Crohn's disease or large bowel inflammation accompanied by ulcers (ulcerative colitis).
- If you have or if you have had heart problems or if you have risk factors for the development of vascular events (e.g. high blood pressure, diabetes, high cholesterol or if you are a smoker).
- If you suffer from liver or kidney disease.
- If you are dehydrated (deficit of water in the body) due to e.g. vomiting, diarrhoea before and after a major operation.
- If you develop swelling of the lower limbs.
- If you suffer from impaired coagulation or other blood disorders including rare liver disorders called hepatic porphyria.
- If you are pregnant, planning to become pregnant, or breast feeding.

If any of the above points concerns you, notify your doctor before you start taking Dolmina™ 50 mg.

Medicines such as Dolmina™ could cause a mild increase in the risk of heart or cerebrovascular events. The risk is greater if you take high doses and in long-term treatment. Therefore do not exceed the recommended dose or length of treatment.

Medicines such as Dolmina™ could mask the symptoms of infectious disease (e.g. headache, fever), therefore it is much more difficult to reveal and treat the complaint appropriately. If you do not feel well and you need to visit a doctor, do not forget to tell him/her that you are taking Dolmina™.

Dolmina™ 50 mg (as well as other non-steroidal anti-inflammatory drugs) could cause some problems with pregnancy. These are reversible on discontinuation of use. If you wish to conceive or if you are having problems conceiving, you must inform your doctor.

Taking other medicines

The effects of Dolmina™ 50 mg and other medicines taken concomitantly may interact with each other. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should inform the doctor especially if you are taking any of the following medicines:
- Lithium or selective serotonin reuptake inhibitors (SSRI), i.e. drugs used for treatment of depression.
- Digoxin (product intended for treatment of heart disease).
- Diuretics (tablets for the excretion of water).
- ACE inhibitors or beta-blockers (group of medicines for the treatment of high blood pressure and heart failure).
- Other non-steroidal anti-inflammatory drugs such as acetylsalicylic acid or ibuprofen.
- Corticosteroids (drugs used to relieve inflammation).
- Drugs used for prevention of blood clotting, e.g. warfarin.
- Medication used for treatment of diabetes, apart from insulin.
- Methotrexate (medication used for some types of cancer or arthritis).
- Cyclosporine (product used after organ transplant).
- Certain anti- infection drugs (quinolones – anti-bacterial medication).

Taking Dolmina™ 50 mg with food and drink

Film-coated tablets are used during meals or after food (to minimise stomach irritation), they should be swallowed whole, not chewed and with a glass of water.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Dolmina™ 50 mg must not be used in the third trimester (last three months) of pregnancy.

Unless it is not absolutely avoidable, Dolmina™ 50 mg should not be administered during the first and second trimester of pregnancy.

Women who plan to conceive must talk to their doctor about usage of this medicine.

Dolmina™ 50 mg passes into human milk, however in such a small amount that the risk of affecting the breast-fed child is only small. Usage of Dolmina™ 50 mg during breast-feeding must always be considered and decided by a doctor. If the doctor considers that treatment with Dolmina™ 50 mg during breast-feeding is required, it should be administered for the shortest possible period of time and breast-feeding should follow always several hours after administration. If there are any changes in the symptoms of the child, advice from a paediatrician should be sought as soon as possible.

Driving and using machines

The product has no effect on attention. However, if you develop some undesirable effects during therapy such as fatigue, vertigo or impaired vision, do not drive or use machines.

Important information about some of the ingredients of Dolmina™ 50 mg

This product contains lactose. If your doctor has told you that you do not tolerate some sugars, seek advice from your doctor before you start using this product.

3. HOW TO TAKE Dolmina™ 50 mg

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dosage. It is important to take Dolmina™ 50 mg in the lowest doses and avoid longer usage than required. Dosage is always determined by the doctor according to the condition and severity of the disease. Based on your therapeutic response the doctor may increase or decrease the dose.

Adults and adolescents from the age of 14 years usually take 1 film-coated tablet of Dolmina™ 50 mg 2 times or 3 times daily.

The period between each dose is less than 4 hours.

Do not take more than 3 tablets in 24 hours.

For pain during menstruation, treatment usually starts with a dose of 50 to 100 mg immediately on the occurrence of the first symptoms. Treatment continues with a dose of 50 mg three times daily for several days as required. If the dose of 150 mg provides no relief to pain during 2 to 3 menstruation cycles, the doctor may recommend an increased dose to 200 mg daily at the next menstruation. Do not exceed the daily dose of 200 mg.

Film-coated tables are used during meals or after meals (to minimise stomach irritation), they should be swallowed whole, not chewed and with a glass of water.

If you feel that the effect of the Dolmina™ 50 mg is too strong or too weak, talk to your doctor.

If you take more Dolmina™ 50 mg than you should

In case of overdose or accidental use of film-coated tablets by a child, seek advice from your doctor or attend the hospital emergency department.

If you forget to take Dolmina™ 50 mg

If you forget to take a tablet, take it as soon as you remember. If the time for the next recommended dose use is near, do not take that tablet. Keep a period of at least 4 hours between each dose.

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Dolmina™ 50 mg can have side effects, although not everybody gets them.

Immediately stop taking the medicine and seek the advice of a doctor, if you experience
- urticaria, sudden swelling around the eyes, pressure on the chest or difficulty breathing.
- bleeding to the gastrointestinal tract or activation of stomach ulcer with possible dark faeces or vomiting of dark stomach content.
- impaired vision.

The risk of developing gastrointestinal complaints (especially impairment of the stomach mucosa) is higher, the greater the dose and length of Dolmina™ 50 mg administration.

Medicines such as diclofenac could cause a mild increase in the risk of heart or cerebrovascular events.

When taking diclofenac (active ingredient in Dolmina™ 50 mg) the following adverse effects, listed according to the frequency of occurrence, may develop:
- Very common (affecting more than 1 in every 10 patients):
  Nausea, vomiting, diarrhoea.
- Common (affecting 1 – 10 in every 100 patients):
  Headache, insomnia, sleeplessness, vertigo, heart burn, meteorism,
- abdominal pain, loss of appetite, stomach or duodenal ulcer1, perforation of the mucosa in the gastrointestinal tract1, hypersensitivity reaction such as rash and itching, fatigue, malaise, increased levels of liver function tests.
- Uncommon (affecting 1 – 10 in every1000 patients): Impairment of haematopoiesis, retention of fluids and salt, vomiting of blood (dark stomach content)1, bleeding from the gastrointestinal tract (manifested as black faeces due to digested blood or blood in faeces)1, liver impairment (liver inflammation, icterus), urticaria, hair loss, swelling (especially in patients with high blood pressure and impaired kidney function).
- Rare (affecting 1 – 10 in every10,000 patients):
  Disorientation, nightmares, anxiety, restlessness, sensitivity disorders, memory disorders, tremor, seizures, impaired vision, tinnitus, temporary hearing problems, stomach inflammation, urinary bladder inflammation.
- Very rare (affecting less than 1 in every 10,000 patients): Non-infectious inflammation of the brain meninges (with symptoms such as stiff neck, headache, nausea, vomiting, fever or loss of consciousness)2, pneumonia, Deterioration of infectious disease, palpitations, heart failure, high blood pressure, inflammation of the oral mucosa or tongue, damage to the oesophagal mucosa, colitis, deterioration of Crohn's disease, new flare-up of colitis, constipation, inflammation of the pancreas, skin rash with blisters or redness, severe forms of skin reactions, impaired kidney function, presence of blood in urine, chest pain, severe allergic reaction associated with swelling, shortness of breath, reduced blood pressure, rapid heartbeat, inflammation of blood vessels.

1 These adverse effects may or may not be accompanied by warning signs. The risk of development increases with increasing dose, and is higher in elderly patients, in persons with a history of stomach or duodenal ulcer (mainly associated with bleeding or perforation of the stomach lining or duodenal mucosa), also in patients receiving long-term acetylsalicylic acid to reduce blood clotting. In these patients the doctor may suggest concomitant administration of medication which protects the lining of the gastrointestinal tract.

2 Especially in patients with connective tissue disorders (systemic lupus erythematodes and some other types of collagen diseases).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist..

5. How to store Dolmina™ 50 mg

Keep out of the sight and reach of children.

Store below 25^{0}C in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the cover. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Dolmina™ 50 mg contains

The active substance is diclofenac sodium 50 mg in 1 film-coated tablet.

The other ingredients are lactose monohydrate, maize starch, colloid anhydrous silica, povidone 25, cellulose powder, magnesium stearate, hypromelose 2910/6, copolymer, acetyl-triethyl-citrate, macrogol 400, macrogol 6000, talc, titanium dioxide, yellow iron oxide, red iron oxide, sodium hydroxide.

What Dolmina™ 50 mg looks like and contents of the pack

Dolmina™ 50 mg are light reddish brown, round, biconvex film-coated tablets with a diameter of 8 mm.

One pack contains 20 50 mg film-coated tablets.

Manufactured by

ZENTIVA, k.s., Prague, Czech Republic

This leaflet was last revised on

29.10.2009

Packed by
Benta SAL, Dbayeh- Lebanon
BPI