

# DOLMINA™ GEL

## 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.**

This medicine is available without prescription. However, you should still use Dolmina™ gel carefully according to the instructions in order to obtain the best benefit possible.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- If your symptoms deteriorate or if there is no improvement within 7 days, immediately visit your doctor.
- 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.

### What is in this leaflet

1. What Dolmina™ gel is and what it is used for
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#### 1. What Dolmina™ gel is and what it is used for

Dolmina™ gel is specially designed to be applied on skin. The product contains the active ingredient diclofenac, which belongs in the group of drugs called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and which suppresses the production of substances that contribute on the development of inflammation.

Dolmina™ gel suppresses inflammation, reduces swelling and pain.

Dolmina™ gel is suitable for local treatment of musculoskeletal diseases of inflammatory or degenerative origin, i.e. to remove pain and inflammation of muscles and joints and it is possible to use it commonly in the following conditions:

- Injury to soft tissues, post-traumatic conditions: injury to tendons, muscles and joints, e.g. in case of sprain, stretch or contusion, back pain (sports injuries).
- To relieve pain in case of mild osteoarthritis of the peripheral joints and back and on the advice of a doctor in the following conditions:
- Localized forms of rheumatism of soft tissues, e.g. tennis elbow, stiff shoulder.

Dolmina™ gel may be used by adults and children from the age of 12. Usage of Dolmina™ gel is suitable also in case of systemic therapy with diclofenac or other anti-inflammatory products.

#### 2. What you need to know before you take Dolmina™ Gel

##### Do not take Dolmina™ gel:

- 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 a reaction after taking these medicines, e.g. bronchial asthma or urticaria.

##### Take special care with Dolmina™ gel in the following cases:

- Do not apply Dolmina™ gel to skin if you have a cut or open wound. Do not apply to skin with rash or eczema.
- Be careful to avoid contact with eyes. If this happens, flush the eyes thoroughly with purified water. In case of persistent complaints see the doctor or pharmacist.
- Dolmina™ gel is intended only for external use. Do not use in the oral cavity. Do not swallow.

##### Other medicines and Dolmina™ gel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are prescribed any other medicines, tell your doctor that you are using Dolmina™ gel.

##### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

##### Driving and using machines

There is no known effect on the ability to drive and use machines.

#### 3. How to take Dolmina™ gel

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

How to use Dolmina™ gel

Unless the doctor determines otherwise, adults and adolescents from

the age of 12 years apply a small quantity of Dolmina™ gel 4 – 3 times daily to the skin at the site of pain or swelling. The required quantity of this medicine varies and depends on the size of the painful or swollen area. Usually a quantity the size of a cherry or a walnut is sufficient. The gel is gently rubbed in and is not covered with any dressing. Wash your hands after application of Dolmina™ gel, unless the treated sites are on the hands themselves.

##### How long should the product be used

If there is no relief within 7 days or in the event of deterioration or adverse effects of the drug, interrupt treatment and seek advice from a doctor.

Do not use Dolmina™ gel for longer than 2 weeks in case of injury to muscles and joints (i.e. sprain, stretching, contusion) or inflammation of tendons or 3 weeks during treatment of pain associated with osteoarthritis, unless longer therapy was prescribed by your doctor.

##### If you take more Dolmina™ gel than you should

Overdose in case of skin application is very unlikely.

If there is accidental ingestion of Dolmina™ gel, contact a doctor immediately.

##### If you forget to take Dolmina™ gel

If you forget to apply Dolmina™ gel at the correct time, apply it as soon as you remember and then continue as usually. Do not apply a double dose.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following allergic signs, STOP using Dolmina™ gel and immediately contact the doctor or pharmacist:

- Skin rash with blisters, urticaria. Occurs in approx. 1 to 10 in 10000 patients.
- Wheezing, shortness of breath or tension on the chest (asthma). Occurs in less than 1 in 10000 patients.
- Swelling of the face, lips, tongue or throat. Occurs in less than 1 in 10000 patients.

##### Less severe adverse effects

Other adverse effects that may occur are usually mild, temporary and harmless. If this concerns you, inform your doctor or pharmacist as soon as possible.

- Skin rash, itching, redness or pain (stabbing) on skin are common after use (in 1 to 10 in 100 patients).
- In very rare cases (in less than 1 in 10000 patients) your skin may be more sensitive to sunlight. Possible symptoms include sunburn with itching, swelling and blisters.

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™ gel

Keep out of the sight and reach of children.

Store below 25°C in the original package, in order to protect from 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™ gel contains

The active substance is diclofenac sodium 0.01 g in 1 g of gel (%1) Gel basis: Ethanol %96, isopropyl alcohol, carbomer 980, ammonium solution %10, monohydrate citrate, purified water.

##### What Dolmina™ gel looks like and contents of the pack

Description of the product: Colourless, clear to slightly opalescent homogeneous gel with the distinctive odour of isopropylalcohol.

Package size: 50 g of gel

Manufactured by  
ZENTIVA, k.s., Prague, Czech Republic

This leaflet was last revised on 6.4.2010

Packaged by  
Benta S.A.L, Dbayeh-Lebanon



PI-163PIL163