

PACKAGE LEAFLET: INFORMATION FOR THE USER

DOLGIT

5 g / 100 g Gel

IBUPROFEN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 any further questions, 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 DOLGIT tablets is and what it is used for
2. Before you take DOLGIT
3. How to take use DOLGIT
4. Possible side effects
5. How to store DOLGIT
6. Further information

1. WHAT DOLGIT IS AND WHAT IT IS USED FOR

DOLGIT gel is analgesic and anti-inflammatory product. It contains the active substance ibuprofen that is effective in the treatment of pain and it has anti-inflammatory effect. Its effect is conditioned by suppressing formation of prostaglandins and other intermediaries which take part in inception and development of these symptoms. Pain moderation, edema reduction and significant improvement of the limb motion appear already after half an hour.

Dolgit gel is intended for topical treatment of sports injuries and accidents related to the violation of the musculoskeletal system such as contusions, sprains, strains and sprains muscle.

After consulting your doctor, Dolgit gel is used in the treatment of acute or chronic inflammation of the painful conditions of the musculoskeletal system (inflammatory) rheumatic diseases of the joints and the spine, swelling and inflammation of the soft tissue (eg Bursa), tendonitis, bursitis, sciatica and shoulder stiffness, muscle pain, lumbago (pain in the lower part of the spine) and neuralgia (nerve inflammation).

2. BEFORE YOU TAKE DOLGIT

Do not take DOLGIT

- Do not use it if you are allergic to Ibuprofen, other NSAIDs or other ingredients of this medicine

- It should not be applied to damaged skin (open wounds or diseased skin), the mucous membranes, eczema and eyes

Take special care with DOLGIT

Dolgit gel is not recommended for use in children and adolescents under 14 years.

Treatment with other nonsteroidal anti-inflammatory drugs, including ibuprofen, can sometimes be associated with renal impairment, peptic ulcer recurrence and can cause allergic bronchial reactions (reactions of the airways) in susceptible persons. Although systemic absorption of ibuprofen which is administered locally is lower than after oral administration, these complications may occur.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

When used according to the instructions, no interactions of DOLGIT have been reported. However, do not simultaneously apply a different product for external use on the same place as Dolgit gel before the consultation with your doctor.

It is useful to take the tablets containing ibuprofen at the same time. Before applying Dolgit gel simultaneously with other preparations, contact your doctor.

Pregnancy and breastfeeding

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

Pregnancy

Contact your doctor if you become pregnant while taking Dolgit gel. Do not use ibuprofen during the first and second trimesters of pregnancy without first consulting your doctor. Dolgit gel should not be used during the last trimester of pregnancy due to increased risk for mother and child.

Long-term use of this medicine on large areas of skin during breastfeeding is not recommended. Your doctor should always decide on the possible use.

Driving and using machines

There is no evidence that DOLGIT gel have effect on the ability to drive and use machines.

Important information about some of the ingredients in DOLGIT

DOLGIT Gel contains 2-propanol which may cause skin irritation.

3. HOW TO TAKE DOLGIT

Always use Dolgit gel as directed in this leaflet. If you are unsure, ask your doctor or pharmacist.

Unless otherwise indicated, the usual recommended dose is:

Apply Dolgit gel 3-4 times daily. Depending on the affected area, apply from 4 to 10 cm, corresponding to 2-5 g gel (100-250 mg ibuprofen). The maximum daily dose is up to 20 g of the gel, corresponding to 1, 000 mg ibuprofen.

After applying Dolgit gel on the affected area, wash your hands (except if you have not applied the gel on your hands).

Directions:

Only for use on the skin ! Do not swallow!
Apply Dolgit gel on the skin and rub gently.

The penetration of the active ingredient through the skin can be enhanced by iontophoresis (a particular form of electrotherapy).

Duration of use:

The physician will determine the duration of treatment . In most cases, daily administration over the course of 2-3 weeks is enough.

No evidence of a therapeutic effect for a short period.

If you feel that the effect of Dolgit gel is too strong or too weak, please contact your doctor or pharmacist.

If you use more Dolgit than you should

In case of Overdose contact your doctor.

If you forget to take Dolgit

If you forgot to apply Dolgit do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dolgit gel can cause side effects, although not everybody gets them.

Uncommon (manifested in 1 to 10 users in 1000):

Hypersensitivity to any component of this product (swelling or redness of the skin, burning or itching, as well as the appearance of small pimples).

Very rare (manifested in 1 out of 10,000 patients):

Hypersensitivity reactions such as difficulty breathing caused by narrowing of the bronchi.

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

5. HOW TO STORE DOLGIT

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use DOLGIT after the expiry date which is stated on the label.

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. FURTHER INFORMATION

What DOLGIT contains

The active substance is ibuprofen. 100 g of Dolgit gel contains 5 g of ibuprofen.

Other substances are: 2-propanol, 2,2 dimethyl-4-hydroxymethyl-1,3-dioxolane, poloxamer, medium chain length triglycerides,, purified water, lavender oil and oil of bitter orange blossoms (neroli oil).

What DOLGIT looks like and contents of the pack

Dolgit gel is clear, colorless gel with a characteristic odor.
Dolgit gel is available in pack of 50 g.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

PRO.MED.CS Praha a.s.
Telčsko 1
140 00 Prague, Czech Republic

Manufacturer of the medicinal product

Dolorgiet GmbH & Co. KG
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