

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### DOLGIT

5 g / 100 g Cream

IBUPROFEN

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*• 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.*

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*• 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 •*

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#### 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 cream is analgesic and anti-inflammatory product for use on the skin.

#### Indications:

For local or supportive treatment in cases of muscular rheumatism , painful degenerative joint disease ( osteoarthritis ), inflammatory rheumatic diseases of the joints and the spine, swelling or inflammation of the soft tissue adjacent to the joints (for example, bursae, tendines, tendon sheaths, ligaments), shoulder stiffness, myalgia, lumbago, bruises, sprains and strains.

#### 2. BEFORE YOU TAKE DOLGIT

##### **Do not take DOLGIT**

- 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
- Do not use it during the last trimester of pregnancy

### **Take special care with DOLGIT**

Dolgit cream is not recommended for use in children and adolescents under 14 years due to lack of available data on the implementation for this age group.

In patients who suffer from asthma, hay fever, swelling of the nasal mucosa or COPD (particularly related to the symptoms of hay fever) and in patients with a hypersensitivity to analgesic and antirheumatic products, there is a higher risk of developing an asthma attack (analgesic intolerance / analgesic asthma), local swelling of the skin or mucous membranes (edema Quincke), or urticaria in comparison with other patients. In these patients Dolgit cream should be applied with precautions and under direct medical supervision. This also applies to patients with hypersensitivity to other substances, manifested by skin reactions, itching or hives.

If complaints persist for more than three days, it is necessary to consult a doctor.

### **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.

### **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 cream. Do not use ibuprofen during the first and second trimesters of pregnancy without first consulting your doctor. Dolgit cream should not be used during the last trimester of pregnancy due to increased risk for mother and child.

#### **Breastfeeding**

Only small amounts of the active ingredient ibuprofen and other substances pass into breast milk. Since at present there are no known negative effects on the child, no discontinuation of breastfeeding is necessary during short-term therapy. However the daily dose of 3-4 daily dosages of 4-10 cm should not be exceeded, and the breastfeeding should be interrupted during long-term therapy.

Breast-feeding women should not use this medicine on their chest.

### **Driving and using machines**

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

### **Important information about some of the ingredients in DOLGIT**

DOLGIT Cream contains propylene glycol which may cause skin irritation.

### **3. HOW TO TAKE DOLGIT**

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

#### **Unless otherwise indicated, the usual recommended dose is:**

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

#### **Directions:**

Only for use on the skin ! Do not swallow!

Apply Dolgit cream on the skin and rub gently. In cases of acute hematoma and sprains Dolgit cream can be applied under occlusion at the beginning of treatment.

The penetration of the active ingredient through the skin can be enhanced by iontophoresis (a particular form of electrotherapy). Dolgit cream should be applied to the cathode (negative pole). The strength of the current must

be 0.1 - 0.5 mA for 5 cm<sup>2</sup> of the surface area of the electrodes and the duration of the treatment for about 10 minutes.

***Duration of use:***

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

No evidence of therapeutic effect for a short period.

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

***If you use more Dolgit than you should***

In case of exceeding the recommended dose, the cream should be removed and the treated area should be washed with water. Specific antidote for intoxication with ibuprofen is not known.

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

***4. POSSIBLE SIDE EFFECTS***

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

***Adverse drug reactions are classified as follows:***

**very common** ( affects 1 or more out of 10 patients ) ;

**common** (affects 1 or more out of 100 , but less than 1 in 10 patients) ;

**uncommon** (affects 1 or more out of 1000 , but less than 1 in 100 patients) ;

**Rare** (affects 1 or more per 10 000 , but less than 1 in 1000 patients) ;

**very rare** ( affects less than 1 in 10,000 patients) ;

**not known** ( frequency cannot be estimated from available data).

**Common** adverse reactions were local skin reactions such as erythema, pruritus, burning, with pustules exanthema and urticaria.

**Uncommonly** observed hypersensitivity reactions are local allergic reactions (contact dermatitis).

**Very rare** are bronchospastic reactions.

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.

Shelf life after first opening: 6 months.

***6. FURTHER INFORMATION***

***What DOLGIT contains***

Active substance: Ibuprofen

100 g of cream contains Dolgit 5 g of ibuprofen in the oil-in- water emulsion.

**Other ingredients are:**

Methyl 4-hydroxybenzoate sodium, medium chain triglycerides , glycerol monostearate, polyoxyethylene 30 stearate, polyoxyethylene 100 stearate, propylene glycol, xanthan gum, lavender oil , orange oil , purified water.

**What DOLGIT looks like and contents of the pack**

Tube containing smooth, soft creamy white to cream color.

Dolgit cream is available in packs of 50 g and 100 g cream.

Not all pack sizes may be marketed.

**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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