

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### DEKSALGIN

12.5 mg / g gel

DEXKETOPROFEN

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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 DEKSALGIN is and what it is used for
2. Before you take DEKSALGIN
3. How to use DEKSALGIN
4. Possible side effects
5. How to store DEKSALGIN
6. Further information

#### 1. WHAT DEKSALGIN IS AND WHAT IT IS USED FOR

DEKSALGIN is an analgesic which belongs to the group of medicines called non-steroidal anti-inflammatory drugs.

The mechanism of action is to prevent or reduce the formation of substances in the body that lead to inflammation and pain in the joints, tendons, ligaments or muscles. DEKSALGIN relieves pain and swelling of the treated area.

DEKSALGIN gel is used for the treatment of painful and inflammatory conditions associated with the joints, tendons, ligaments and muscles.

#### 2. BEFORE YOU TAKE DEKSALGIN

##### **Do not take DEKSALGIN**

- If you are allergic (hypersensitive) to Dexketoprofen trometamol, ketoprofen, tiaprofenic acid, UV blockers, perfumes or to any ingredient of DEKSALGIN gel (see section 6);
- if you are allergic to aspirin or its derivatives or other non-steroidal anti-inflammatory drugs (such as ibuprofen);

- If you plan to apply DEKSALGIN gel on the eye or eye area, mucous membranes (mouth, nose and genitals), open wounds or broken skin, such as in the case of limited purulent inflammation of the skin, ulcers or tumors;
- If you intend to expose treated areas to sun, UV rays (solarium) during treatment and two weeks after discontinuation of treatment.

Stop using DEKSALGIN gel immediately if it comes to the development of skin reactions, including skin reactions that may occur after the simultaneous application of products containing octocrylene (octocrylene is a protective factor against the sun, which role is to prevent photodegradation, and is contained in the number of cosmetic products such as shampoos, after-shave preparations, shower gels, skin care creams, lipsticks, anti-aging creams, preparations for removing makeup, hairspray).

### ***Take special care with DEKSALGIN***

After applying the gel, do not wear tight clothing or clothing that does not allow air circulation around the area on which the gel is applied.

Exposure of the treated areas to sunlight, even during cloudy days, or UV rays in a tanning bed, can cause potentially serious skin reaction (photosensitization). Therefore, it is necessary to:

- Protect the areas with clothing during treatment and two weeks after completion of treatment, in order to avoid the risk of photosensitization;
- wash your hands thoroughly after each application of DEKSALGIN gel.

### ***Taking other medicines***

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

It is unlikely that there will be interactions with other medicines because DEKSALGIN gel is applied to the skin.

### ***Children and adolescents***

DEKSALGIN gel should not be used in children under 6 years.

### ***Pregnancy and breastfeeding***

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

The safety of DEKSALGIN gel during pregnancy and breastfeeding has not been evaluated, and DEKSALGIN Gel should not be applied during pregnancy.

It is not known whether Dexketoprofen is excreted into breast milk and it should not be used during breastfeeding.

### ***Driving and using machines***

DEKSALGIN does not affect your ability to drive or use machines.

## ***3. HOW TO USE DEKSALGIN***

The usual regime of administration is two or three times daily.

The used amount of gel depends on the surface area to which the gel is applied. Apply the gel by gently massaging it to enhance absorption.

The total daily dose should not exceed 7.5 g per day, which corresponds to approximately 14 cm of gel.

The treatment should last a maximum of 7 days.

If there is no improvement or the condition gets worse, you should contact your doctor.

### ***If you use more DEKSALGIN than you should***

It is unlikely that there will be an overdose, considering that it is applied to the skin. If the gel is swallowed, contact your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## ***4. POSSIBLE SIDE EFFECTS***

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

**Uncommon side effects** (in less than 1 in 100 people):

dermatitis (redness and inflammation of the skin), including allergic skin reactions.

**Rare side effects** (less than 1 in 1,000 people):

cases of severe side effects, such as bullous eczema (eczema with blisters) and phlyctenular eczema (eczema on the face and neck which are the cause of phlycten or clusters of cells on the cornea), which may expand or become generalized.

**Very rare side effects** (less than 1 out of 10,000 people):

Allergic reactions are manifested as hives (rash with itching), and / or difficulty breathing.

Frequency of occurrence cannot be assessed on the basis of available data:

severe skin reactions during exposure to sunlight (photosensitivity), which can be manifested as redness and swelling of the skin, and sometimes the formation of bubbles.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

## ***5. HOW TO STORE DEKSALGIN***

Keep out of the reach and sight of children.

Do not store above 25 °C.

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

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. FURTHER INFORMATION***

### ***What DEKSALGIN contains***

The active substance is Dexketoprofen trometamol. 1 g of gel contains 18.5 mg of Dexketoprofen trometamol equivalent to 12.5 mg of Dexketoprofen.

Other ingredients are: carbomer homopolymer, diethylene glycol monoethyl ether, macrogol (polyethylene glycol 8000 P), lavender oil, ethanol (96%), and purified water.

### ***What DEKSALGIN looks like and contents of the pack***

The gel is in an aluminum tube with an internal epoxy varnish layer with HDPE plastic cap which is placed in a cardboard box. Size of packaging is 60 g.

### ***Regime of dispensing***

The medicine is issued without doctor's prescription.

***Manufacturer***

NOBEL İLAÇ SANAYİİ VE TİCARET A.Ş.  
Ümraniye 34768 İstanbul Türkiye

***Manufacturer of the medicinal product***

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