

NIMULID TRANSGEL

10 mg/g, gel, 30 g

NIMESULIDE

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

1. WHAT NIMULID TRANSGEL IS AND WHAT IT IS USED FOR

The basic mechanism of action is the blockage of the enzyme cyclooxygenase, which is crucial in the process of formation of so called prostaglandins.

Nimesulide is a well-known medicine from a group of nonsteroidal anti-inflammatory medicines which exhibits all the therapeutic effects which are essential for this group, that is, it suppresses inflammation, relieves pain and reduces fever.

Prostaglandins in healthy body exhibit a number of beneficial effects on the kidneys, lungs, gastric-intestinal system and brain, while their formation in some diseases is extremely damaging and affects the deterioration of flow and image of the disease.

Nimesulide targets and blocks the enzyme cyclooxygenase, type 2, which is participating in the production of harmful prostaglandin during inflammation, infections, injuries, etc.

In addition, it increases the synthesis or blocking of some other enzymes and chemical mediators which are relevant in the inflammatory reaction, during the development of elevated temperatures or pain.

Therefore, in the form of a gel, it is used in children older than 12 years and adults for the treatment of inflammation and pain after injuries of tendons and joints.

Nimulid Transgel is applied topically (applied to the skin) in order to reduce the pain with sprains to joints and inflammation of tendons after different types of injuries.

2. BEFORE YOU TAKE NIMULID TRANSGEL

Inform the doctor if you are taking other medicines, you have a chronic disease, a metabolic disorder, hypersensitivity to medicine or have had an allergic reaction to some of them.

Before you begin using Nimulid Transgel tell your doctor:

- If you have an allergy to any of the medicines used for inflammation or pain
- If you are pregnant
- If you are breast-feeding your baby.

Nimulid Transgel should not be used:

If you have hypersensitivity on nimesulide, or auxiliary substances in Nimulid Transgel,

- in patients who receive aspirin or other medicines that block the formation of prostaglandins,
- in patients with acute allergic reactions, such as colds, nettle rash or respiratory problems,
- In damage or infection of the skin,
- Simultaneously with other products that are locally applied to the skin,
- in children under 12 years.

Warnings and precautions

Nimulid Transgel should be applied only on undamaged skin. It shouldn't be used if affected regions contain wounds, abrasions or infections.

When using the gel you should take care that it does not get into the eyes, nose and mouth cavity, as well as on the genital area or the anus.

If during use on the skin you notice pronounced redness, signs of irritation or burning, the use of Nimulid Transgel should be discontinued immediately and you should contact your doctor.

During the administration of Nimulid Transgel you should not go sunbathing or to a tanning salon.

En route, Nimulid Transgel can get more intense yellow color. This is a common phenomenon that has no effect on the efficiency and safety of the medicine.

Pregnancy and breastfeeding

Before you start taking medicine, consult your doctor or pharmacist.

If you know, or think you may be pregnant, or if you are breastfeeding your baby, don't use Nimulid Transgel.

Driving and using machines

Use of Nimulid Transgel does not affect your ability to drive a car or work with machines that can hurt you.

What you need to be aware if you are taking other medicines

Note that this information may apply to medicines that you no longer take, as well as the medicines that you plan to take in the future. Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines that are purchased without a prescription.

When nimesulide is rubbed onto the skin, only the minimum quantities of the medicine get in the bloodstream. It's unlikely that they can significantly affect the action of other medicines that are used at the same time. In oral administration it interacts with furosemide, fenofibrate, salicylic acid, tolbutamide and theophylline, but not with warfarin

What you need to know about other substances contained in the medicine Nimulid
Not applicable.

3. HOW TO USE NIMULID TRANSGEL

If you think Nimulid Transgel is too weak, or has strong effect on your system, contact your doctor or pharmacist.

Nimulid Transgel is designed only for external use.

After extrusion from the tube, approximately 4- 5 cm gel should be applied to the surface evenly and rubbed into the skin. After rubbing it you should wait until the surface of the skin is dry, to avoid subsequent contamination of clothing. If a doctor does not tell you otherwise, the gel should be applied 2- 3 times a day and should not be used for more than 7 to 15 days.

Daily frequency of applying gel should not be increased without consulting the competent doctor.

It is not necessary to rub the gel intensively into the affected area, and you should not put elastic straps over it. After using the gel, you should wash your hands.

If you take more medicine than you should

If you have taken a higher dose of Nimulid Transgel than you should, speak with your doctor or pharmacist.

If you forget to take Nimulid Transgel

Never take a double dose to replace the forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nimulid Transgel can cause side effects. Side effects are rare and mild. They are usually in the form of local stimulation, redness, and rashes, exfoliating and itching. You may experience transient loss of color on skin or transfer of color on clothing.

If you experience stronger irritation to the skin, stop using the medicine immediately and report to the competent doctor. He/she will, if necessary, prescribe appropriate treatment.

5. HOW TO STORE NIMULID TRANSGEL

Keep it out of reach of children.

It must be stored in their original packaging, in a dry place, protected from the direct effects of light and high temperatures. No need to keep it in the fridge.

Shelf life

It should not be used after the expiration date indicated on the package.

Shelf life is 3 years from the date of production.

Dispose of medicine in accordance with the applicable regulations.

6. ADDITIONAL INFORMATION

What is Nimulid Transgel contains
Active substance is nimesulide.

The contents of the active substances:
1 g of gel contains 10 mg of nimesulide.

Other substances:

Hydroxypropylcellulose,
Carbomer-940,
ethanol, concentrated,
water, purified,
triacetin,
N, N-dimethyl acetamide,
phosphoric acid, concentrated,
corrigent fragrances (MSC-03 and G 0106).

Packaging

Medicinal products in a cardboard box with aluminum-tube containing 30 grams of product. The gel is transparent and yellow in color.

Pharmacotherapeutic group: non-steroidal anti-inflammatory medicines (NSAIDS) for local use.

ATC code: M02AA

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Panacea Biotec Ltd.
B 1/ Extn/A-27, Mohan Co-operative Industrial Estate
Mathura Road
New Delhi – 110044, India

Manufacturer of the medicinal product

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