

PACKAGE LEAFLET: INFORMATION FOR THE USER

NEOFEN PLUS

50 mg/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 NEOFEN PLUS is and what it is used for
2. Before you take NEOFEN PLUS
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1. WHAT NEOFEN PLUS IS AND WHAT IS IT USED FOR

NEOFEN PLUS gel contains the active substance Ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This medicines reduces pain and inflammation.

Neofen plus gel is used for the local treatment of rheumatic pain, muscle pain, backache, pain and swelling caused by sprains, strains and other sports injuries and neuralgia (pain caused by nerve damage).

The gel is intended for external use only.

2. BEFORE YOU TAKE NEOFEN PLUS

Do not take NEOFEN PLUS

- If you are allergic (hypersensitive) to the active substance or any the other ingredients of Neofen plus 50 mg / g gel
- If you are allergic (hypersensitive) to aspirin or similar medicines (eg, nonsteroidal anti-inflammatory drugs)
- If you suffer from asthma
- If you have rhinitis (allergic rhinitis) or urticaria (hives)
- If you have open wounds on the skin or if you have a damaged, inflamed skin

- If you have a skin disease

Take special care with NEOFEN PLUS, so you must tell the doctor if you

- If you have or have had an ulcer or other problems with your stomach or intestines
- If you have suffered or are suffering from asthma or wheezing attacks
- If you have problems with your kidneys
- If you suffer from asthma or other allergic diseases

Do not expose parts of the body to which you apply Neofen plus gel to sunlight, to avoid the possible occurrence of hypersensitivity reactions, eg. skin rash.

If you notice the appearance of skin rash stop using Neofen plus gel.

Taking other medicines

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

This also applies to herbal medicines and homeopathic remedies.

Neofen plus gel can have an effect on other medicines, while some other medicines may affect the effect of Neofen plus gel. This applies to:

- medicines to lower your blood pressure (eg. Atenolol)
- medicines used to thin the blood (eg, warfarin)
- Aspirin or other NSAIDs.

Pregnancy and breastfeeding

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

NEOFEN PLUS in pregnant and nursing women should not be used.

Driving and using machines

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

Important information about some of the ingredients in NEOFEN PLUS

Neofen Plus Gel contains propylene glycol which may cause skin irritation.

3. HOW TO TAKE NEOFEN PLUS

When applying NEOFEN PLUS gel strictly follow the instructions given to you by your doctor.

NEOFEN PLUS gel is for topical application only. Never take Neofen plus gel by mouth.

Adults, elderly and children over 12 years

Squeeze 50-125 mg (4-10 inches) of gel to the affected area. Massage it gently until it is completely absorbed.

Leave at least 4 hours between doses. Do not apply the gel more than 4 times in 24 hours. Wash your hands after using this medicine, unless you are applying it on your hands.

Do not use it on broken skin, on the lips, genitals or near the eyes. Do not apply the gel under the bandage, patch or gauze.

If your symptoms persist for more than 14 days consult your doctor.

Children under 12 years

This medicine should not be used in children younger than 12 years.

If you have accidentally swallowed gel NEOFEN PLUS

If you or someone else have accidentally swallowed NEOFEN PLUS gel, tell your doctor immediately.

If you accidentally swallow the gel, immediately rinse your mouth and contact your doctor or nearest hospital. Take the remaining gel or leaflet with you to health professionals. If swallowed, the gel may cause nausea and vomiting.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, **NEOFEN PLUS** can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare. If you experience wheeziness, breathing difficulties, swelling of eyelids, face or lips or itching (especially affecting the whole body), then immediately contact your doctor.

Side effects include:

- Itching or redness of the skin
- Burning sensation
- Sore or weeping spots on the skin
- Abdominal pain (stomach ache) or other abnormal stomach symptoms
- Kidney problems (particularly in people who have had a kidney disease in the past).

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.

Reporting of suspected side effects

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 NEOFEN PLUS

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use **NEOFEN PLUS** 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