

Patient Information Leaflet

LOFNAC GEL

Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate and Menthol Gel

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use LOFNAC GEL carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 7 days.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What LOFNAC GEL is and what it is used for
2. Before you use LOFNAC GEL
3. How to use LOFNAC GEL
4. Possible side effects
5. How to store LOFNAC GEL
6. Further information

1. What LOFNAC GEL is and what it is used for

LOFNAC GEL contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin and is used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles. LOFNAC GEL can be used to treat:

- Muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries)
- Tendonitis (e.g. tennis elbow)
- Mild arthritis

2. Before you use LOFNAC GEL DO NOT use LOFNAC GEL if you:

- Have an allergy (hypersensitivity) to any of the ingredients in the product (see Section 6 'What LOFNAC GEL contains').
- Have ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever or inflammation, such as aspirin or ibuprofen.
Symptoms of an allergic reaction to these medicines may include: asthma, wheezing or shortness of breath; skin rash or hives; swelling of the face or tongue; runny nose.
- Are using any other medicine containing diclofenac or are taking oral NSAIDs such as aspirin or ibuprofen.

This medicine is not recommended for use in children under 12 years of age.

Take special care with LOFNAC GEL

- Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds.
- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.
- If you have or have ever had asthma speak to your doctor or pharmacist before using the gel.

Taking other medicines

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

Do not use LOFNAC GEL if you are already taking diclofenac tablets or other NSAID pain/inflammation tablets (e.g. aspirin or ibuprofen).

Pregnancy and breast-feeding

LOFNAC GEL should not be used if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

LOFNAC GEL, when used as directed, is not expected to have any effect on your ability to drive or use machines.

3. How to use LOFNAC GEL

- Always use LOFNAC GEL exactly as your doctor has told you.
- The gel is for external use only. Do not use it in your mouth. Inform your doctor immediately in case of accidental swallowing.
- Do not put LOFNAC GEL in your eyes. If this happens, rinse your eyes well with clean water.
- See your doctor or pharmacist if any discomfort persists.

Adults and adolescents over 12 years

- Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area 3 to 4 times a day, slowly rubbing into the skin. The amount needed will vary depending on the size of the painful or swollen area; an amount ranging in size from a 1 penny to a 2 pence piece will usually be sufficient. You may notice a slight cooling effect when you rub the gel in.
- Do not rub the gel into cuts, open wounds or any other area where the skin is abnormal.
- Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
- Wash your hands after rubbing in LOFNAC GEL, unless your hands are the site being treated.

This medicine is not recommended for use in children under 12 years of age.

Do not use LOFNAC GEL for more than:

- 7 days unless longer treatment is recommended by a doctor. If the pain and swelling do not improve within 7 days, or worsen, speak to your doctor. If symptoms do not improve within this time, or they get worse, consult your doctor.
- If you use more LOFNAC GEL than you should
- If you or a child accidentally swallows LOFNAC GEL, contact your doctor or accident and emergency department immediately.

If you forget to use LOFNAC GEL

If you miss your application of LOFNAC GEL at the correct time, apply it as soon as you remember then carry on as normal. Do not apply a double quantity to make up for a forgotten application.

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

4. Possible side effects

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

If you experience any of the following signs of an allergic reaction stop using LOFNAC GEL and tell your doctor or pharmacist immediately:

- Skin rash with blisters, hives
- Wheezing, shortness of breath or asthma/feeling of tightness in the chest
- Swelling of the face, lips, tongue or throat.

Other side effects which may occur are usually mild, passing and harmless (if you are concerned, tell your doctor or pharmacist as soon as you can):

- Skin rash, itching, reddening or smarting (sharp, stinging pain) of the skin.
- Your skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.
- Asthma has been rarely reported in patients using topical NSAIDs.

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

5. How to store LOFNAC GEL

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use LOFNAC GEL after the expiry date stated on the carton and tube.

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 LOFNAC GEL contains

Each gm of LOFNAC GEL contains 1.16g of diclofenac diethylamine BP equivalent to Diclofenac Sodium 1.00 % w/w; 3.00 % w/w of Linseed oil BP, 10.00 % w/w of Methyl salicylate BP, 5.00 % w/w of Menthol BP.

Carbomer 940, Disodium Edetate, Butylated Hydroxy Toluene, Propylene Glycol, Benzyl Alcohol, Isopropyl Alcohol, Hydrogenated Caster Oil (Polyoxyl 40), Triethanolamine, Polysorbate 80, Butylated Hydroxy Anisole, Citric acid monohydrate, Purified water.

What LOFNAC GEL looks like and contents of the pack

Printed tubes with sealed nozzle fitted with white colour screw cap, available in packs of 30g.

LOFNAC Gel are manufactured by

Bliss GVS Pharma Ltd., Saki Vihar Road, Andheri (East), Mumbai - 400 072,

INDIA.

This leaflet was revised in July 2015.