

Mobilat N[®] gel

Composition

Pharmaceutically active ingredients:

100 g gel contain:
Mucopolysaccharide
polysulfuric acid ester 0.2 g
Salicylic acid 2.0 g

Other ingredients:

Carbomers, disodium edetate, ethanolamine, isopropyl alcohol, macrogol-20-glycerolmonooleate, purified water, rosemary oil.

Presentation and content

Mobilat N gel is available in packages containing 50 g of gel.

Mobilat N gel contains a combination of two active substances, which, when used externally, are effective in the treatment of blunt injuries.

Manufacturer

Mobilat Produktions GmbH
Luitpoldstrasse 1
D-85276 Pfaffenhofen/Ilm
Germany

Pharmaceutical entrepreneur

DAICHI SANKYO EUROPE GmbH
Zielstattstrasse 48
D-81379 Munich
Germany

Indications

Apply Mobilat N gel for the supportive topical treatment of painful, blunt trauma (sprains, strains or contusions) as a result of e.g. sports injuries.

Please see a doctor if symptoms persist for more than 3 days.

Contra-indications

When should Mobilat N gel not be used?

Do not use Mobilat N gel

- if you are hypersensitive to either of the active substances or to any of the excipients of Mobilat N gel
- on open lesions, inflamed or infected skin, eczema or mucous membranes.

When should you consult your physician before using Mobilat N gel?

The cases in which you may only take Mobilat N gel under certain conditions and with special precaution are described below.

Please consult your physician about this. You should also do this if the information has applied to you at an earlier point in time.

Patients with disorders of the kidneys should ask the physician before using Mobilat N gel.

What should you consider in babies and infants?

Babies and infants should not be treated with Mobilat N gel, except the physician has expressly permitted it.

Dosage, mode and duration of treatment

The following information applies unless your physician has prescribed a different use of Mobilat N gel. Please follow the directions for use because, otherwise, Mobilat N gel may not have the desired effect.

How much Mobilat N gel should you use and how often should you apply it?

You should apply Mobilat N gel 2–3 times daily. Depending on the size of the area to be treated, a length of 5 to 15 cm of gel is necessary.

How should you use Mobilat N gel and when should you apply it?

For external use only. Do not swallow.

Apply Mobilat N gel to the affected body areas and rub gently in. Before applying a dressing, Mobilat N gel should be allowed to dry on the skin for a few minutes. Use of occlusive dressings is not recommended.

Note for the physician:

Mobilat N gel may be used with advantage in combination with physiotherapies as for example ionto- and phonophoresis (for iontophoresis the gel has to be applied under the cathode).

For how long should you use Mobilat N gel?

In general, the duration of the treatment is not limited.

In chronic diseases a long-term treatment may be indicated. To be on the safe side, consult your physician about this.

Side effects

Which side effects may occur during a treatment with Mobilat N gel?

Like all medicines, Mobilat N gel can cause side effects, although not everybody gets them. For the assessment of the side effects, the following frequency rating was used:

Very common	in more than 1 in 10 patients treated
Common	in less than 1 in 10, but more than 1 in 100 patients treated
Uncommon	in less than 1 in 100, but more than 1 in 1.000 patients treated
Rare	in less than 1 in 1.000, but more than 1 in 10.000 patients treated
Very rare	in less than 1 in 10.000 patients treated, including isolated reports

Uncommon: local skin irritations

Very rare: contact allergies.

If you notice adverse reactions that have not been indicated in this package insert, please inform your physician or pharmacist.

Which measures are to be taken in the case of side effects?

If side effects occur, you should discontinue the use of Mobilat N gel. Usually, the complaints will then subside without any further measures.

infants?

Babies and infants should not be treated with Mobilat N gel, except the physician has expressly permitted it.

What should you consider during pregnancy and lactation?

During pregnancy and lactation you should not use Mobilat N gel on large skin areas and only after consulting your physician. Nursing mothers should not apply Mobilat N gel to the breast region.

Precautions for use and special notes

Which precautions have to be observed?

Apply Mobilat N gel only to intact skin. Avoid contact to injured skin, open wounds, the eyes or mucous membranes. You should ensure that your child's hands are prevented from coming into contact with skin areas where the product has been rubbed in.

Interactions with other drugs

Which other drugs are influenced in their efficacy by Mobilat N gel?

The salicylic acid in Mobilat N gel may increase the permeability of the skin for drugs which are applied to the same region. When Mobilat N gel is applied to large skin areas or over a prolonged period of time, unwanted effects of methotrexate and the hypoglycemic effect of agents from the sulfonyl urea group may be increased.

If side effects occur, you should discontinue the use of Mobilat N gel. Usually, the complaints will then subside without any further measures.

Notes and information on the shelf life of the drug

The expiry date for this package is indicated on the carton and at the bottom of the tube. Do not use the package after this date.

How should you store Mobilat N gel?

Mobilat N gel should be stored below 30°C. Like all drugs, Mobilat N gel must be stored out of the reach of children.

Information dated: April 2008

Additional information for the patient



Opening of the tube:

Perforate the protective foil covering the opening of the tube with the thorn in the cap by pushing and turning simultaneously. Make sure that the foil has been completely removed.

Each tube of Mobilat N gel is checked for its proper weight. In order to assure the correct closure of the tube during the filling process, an air gap is technically required. However, this does not affect the filling weight.

THIS IS A MEDICAMENT

- A drug is a product which acts on your health and its consumption could be dangerous when you do not follow the instructions.
- Follow strictly the doctor's prescriptions, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist know the medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor

KEEP ALL MEDICAMENTS OUT OF REACH OF CHILDREN

Council of Arab Health Ministers and Union of Arab Pharmacists.