Patient Information Leaflet

SCHEDULING STATUS

S3

NORFLEX GEL FORTE, benzydamine hydrochloride 5,0 g per 100 g gel.

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

Norflex Gel Forte is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Norflex Gel Forte carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Norflex Gel Forte with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What Norflex Gel Forte is and what it is used for
2. What you need to know before you use Norflex Gel Forte
3. How to use Norflex Gel Forte
4. Possible side effects
5. How to store Norflex Gel Forte
6. Contents of the pack and other information

1. What Norflex Gel Forte is and what it is used for

Norflex Gel Forte is used for the short-term treatment of pain caused by inflammatory conditions. It works by stopping pain and swelling (inflammation) to treat aches and pains including sprains, strains, sore muscles and after-effects of fractures.

2. What you need to know before you use Norflex Gel Forte

Do not use Norflex Gel Forte:

- if you are hypersensitive (allergic) to benzydamine hydrochloride or any of the other ingredients of Norflex Gel Forte
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with Norflex Gel Forte

- if you have a history of asthma
- if you are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory (NSAID) drugs
- do not apply Norflex Gel Forte near your eyes or mucosal surfaces such as your mouth or nose as irritation may occur.

Other medicines and Norflex Gel Forte

Always tell your health care provider if you are takin any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machinery

It is not always possible to predict to what extent Norflex Gel Forte may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Norflex Gel Forte affects them.

3. How to use Norflex Gel Forte

Do not share medicines prescribed for you with any other person.

Always use Norflex Gel Forte exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure

Lightly massage Norflex Gel Forte into the affected area three times a day.

It can be used up to six times a day in more severe conditions at the discretion of your doctor.

35 to 85 mm length of gel when squeezed out of the tube or 1 to 2,5 g of the gel should be used for each application.

Do not use Norflex Gel Forte for longer than 10 days.

Your doctor will tell you how long your treatment with Norflex Gel Forte will last.

If you have the impression that the effect of Norflex Gel Forte is too strong or too weak, tell your doctor or pharmacist.

If you use more Norflex Gel Forte than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

If you forget to use Norflex Gel Forte

Do not apply a double dose to make up for forgotten individual doses.

4. Possible side effects

Norflex Gel Forte can have side effects.

Not all side effects reported for Norflex Gel Forte are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your health care provider for advice.

If any of the following happens, stop using Norflex Gel Forte and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Anaphylactic reaction (a serious, potentially life-threatening allergic reaction that is marked by swelling, hives, low blood pressure and difficulty breathing)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Norflex Gel Forte. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency not known:

- Photosensitivity reactions (immune system skin reactions that is triggered by sunlight)
- A wide range of local skin reactions (the skin may return to normal when treatment is stopped)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Norflex Gel Forte.

Alternately you can contact iNova Pharmaceuticals on +27 (0) 11 087 000. Website: www.inovapharma.co.za

5. How to store Norflex Gel Forte

Store all medicines out of reach of children.

Store at or below 30 °C. Protect from light.

Do not use after the expiry date stated on the tube or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

The active ingredient is benzydamine hydrochloride 3,0 g per 100 g gel.

The other ingredients are glycerol, hydroxyethyl cellulose, isopropyl alcohol, lavender perfume, purified water.

What Norflex Gel Forte looks like and contents of the pack

Clear colourless to slightly opalescent gel with an odour of lavender/isopropyl alcohol.

White aluminium laminated tubes containing 30 g or 75 g.

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

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Access to the corresponding Professional Information

Full professional information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals (Pty) Ltd