



Bayer HealthCare Manufacturing S.r.l. (Segrate)

Artwork date: 06/02/2017
Version n°: 02
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Technical drawing:	PZ 2585A-4 DRA_90038	Item n°:	84790079	Replaces:	81026327
Laetus-code n°:	54	Client:	044		
Bar-code n°:					
Name:	Nerisona Forte	Country:	Great Britain (Meadow)		
Colors:	Black	Format label:			
Approved.:		Date:			



MEADOW

Patient information Leaflet

**Nerisone® Forte Ointment
Nerisone® Forte Oily Cream**

(diflucortolone valerate)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

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

1. What Nerisone Forte is and what it is used for

Nerisone Forte contains the active ingredient diflucortolone valerate, which is a type of medicine known as a topical corticosteroid (or steroid). "Topical" means applied to the skin. Topical corticosteroids are used to reduce the redness and itchiness caused by certain skin problems.

Nerisone Forte is used for the short term treatment of severe and resistant inflammatory skin conditions such as eczema, dermatitis and certain types of psoriasis, where there is no infection and where milder treatments have not been effective.

Nerisone Forte comes in two forms to suit different conditions of the skin:

Nerisone Forte Ointment is suitable for very dry skin conditions. It provides a layer of oil to prevent water loss, helping to heal dryness and scaling.

Nerisone Forte Oily Cream is suitable for skin conditions which are neither weeping nor very dry. It makes the skin slightly greasy without retaining heat or fluid.

Your doctor will prescribe the correct product to treat your specific condition.

2. Before you use Nerisone Forte

Do not use Nerisone Forte if you:

- are **allergic** (hypersensitive) to any of its ingredients (see section 6)
 - have a skin problem on your **face** (especially **eyes**)
 - have **acne**
 - have a condition in the **genital/anal** area (unless recommended by your doctor)
 - suffer from a **viral** skin condition such as cold sores, herpes, shingles or chicken pox
 - have a skin **reaction after a vaccination** in the area to be treated
 - have a **bacterial** or **fungal** infection for which you are not receiving treatment
 - are **pregnant**
 - are **breast-feeding** and have a skin condition on your breast
- Tell your doctor if you believe any of the above conditions apply to you.

Nerisone Forte should not be used to treat children under 5 years old and should not be used to treat nappy rash.

Take special care with Nerisone Forte:

Tell your doctor if:

- you have a skin irritation on the lower legs related to circulatory problems called **stasis dermatitis** or **leg ulcers** as you may have an increased risk of allergic reaction to Nerisone Forte.
- a **new infection occurs during the treatment** as your doctor may also prescribe a medicine to treat the infection.

- you suffer from **psoriasis**, because Nerisone Forte may make some types of psoriasis worse.
- you have a **skin infection**, since this may also worsen.
- you suffer from **glaucoma** - high pressure in the eye which may cause loss of vision

Do not apply more Nerisone Forte or use it for longer than your doctor tells you.

Nerisone Forte **must not** come into contact with your eyes. Rinse with cold water if accidental contact occurs.

Do not use Nerisone Forte for more than one or two weeks due to an increased risk of side effects. If treatment with Nerisone Forte is necessary for longer than one week your doctor may need to monitor closely the progression of your treatment. If further treatment is needed a weaker strength of Nerisone should be used.

Children

Nerisone Forte must not be used in children less than 5 years of age.

Avoid long term continuous treatment with this medicine. Nerisone Forte may reduce the activity of the adrenal glands causing a lower resistance to disease. Similar effects may occur in a baby after extensive use of Nerisone Forte by its mother during the last weeks of pregnancy or when she is breast-feeding the baby.

Using dressings over the treatment area

If your doctor has recommended that the affected areas of your skin on which Nerisone Forte is used are also covered with a dressing, you must follow his/her instructions on how often the dressing needs to be changed and how much Nerisone Forte you should use. Generally, each dressing should not be left for more than 24 hours. In some cases your doctor may recommend the dressing is changed every 12 hours. Do not leave the dressing for longer than you have been told to. Always look carefully at the skin when you change the dressing. If your skin looks more inflamed than before or if any pimples containing pus have appeared, stop using the dressing and contact your doctor as soon as possible. You should not use dressings on your face.

Taking other medicines

Nerisone Forte has not been shown to interact negatively with any other medications. As a general precaution you should





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

Pregnancy and breast-feeding

Even at the usual dose, the possibility of a very small risk to the development of a baby in pregnant women treated with Nerisone Forte cannot be entirely ruled out. **Therefore, this medicine should not be used if you are pregnant, trying to become pregnant or are breast-feeding unless considered essential by your doctor.**

If a doctor prescribes this medicine to you it should not be used on large areas of the skin.

If you are breast-feeding, Nerisone Forte should not be applied to your breasts.

Driving and using machines

Nerisone Forte does not impair your ability to drive or operate machinery.

3. How to use Nerisone Forte

Always use your medication exactly as directed by your doctor. Wash your hands before and after using Nerisone Forte. Gently spread a **thin layer** of Nerisone Forte onto the affected area of your skin. **Do not** use large amounts or apply more frequently than your doctor has advised.

Dosage

Adults:

Typical dosage: apply thinly twice a day. When the condition improves your doctor may suggest using Nerisone Forte once a day. It is only intended for short-term use, 1–2 weeks. Nerisone Forte is very strong and you should not use more than 60 g in a week. After improvement if further treatment is necessary your doctor may prescribe a weaker strength of Nerisone.

Children 5 years of age and over and adolescents:

Typical dosage: apply thinly twice a day. When your condition improves your doctor may suggest using Nerisone Forte once a day. Use Nerisone Forte with care and for no longer than 1-2 weeks.

Children under 5 years of age:

Nerisone Forte must not be used in children under 5 years of age.

If accidentally swallowed

If you or someone else swallows Nerisone Forte it is unlikely to be harmful but contact your doctor or pharmacist if you are at all concerned.

If you forget to use Nerisone Forte

If you have forgotten to use your medicine, do not make up for it by using extra. When you remember, use the next prescribed dose and continue with your treatment schedule.

4. Possible side effects

Like all medicine Nerisone Forte can cause side effects, although not everybody gets them.

Rarely an **allergic reaction** to Nerisone Forte may occur. If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately. Sometimes after using Nerisone Forte, your skin might feel like it is burning, itching or irritated. Your skin may also look red or flushed.

If you experience the following symptoms while you are using this medicine contact your doctor:

- thinning of the skin on or around the treated area
- acne-like spots
- stretch marks (striae)
- inflammation of the skin around the mouth (peri-oral dermatitis)
- groupings of fine blood vessels becoming prominent under the skin (telangiectasia)
- increased hair growth (hypertrichosis)
- glaucoma (increased pressure in the eye)

Side effects are more likely to occur when Nerisone Forte is applied to large areas (10% or more) of the body and used for long periods of time (more than 2 weeks), especially if waterproof dressings are used. The risk of glaucoma is also increased if Nerisone Forte is applied to the skin around the eyes.

Extremely rarely Nerisone Forte can cause side effects such as a decrease in the production of natural hormones by the adrenal glands, which can lead to illness such as Cushing's syndrome (hypercorticism).

Reporting of 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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nerisone Forte

Keep out of the sight and reach of children.

Do not use after the expiry date on the pack.
Nerisone Forte Oily Cream: Store below 30°C. After first opening the tube, Nerisone Forte Oily Cream should be used within 3 months.

6. Further information

What Nerisone Forte contains:

Nerisone Forte Ointment and Nerisone Forte Oily Cream contain 0.3% of the active ingredient diflucortolone valerate.

Inactive ingredients:

Nerisone Forte Ointment: liquid paraffin, white soft paraffin, Lunacera M (microcrystalline wax) and castor oil (hydrogenated).

Nerisone Forte Oily Cream: white beeswax, liquid paraffin, white soft paraffin, Dehymuls E and purified water.

What Nerisone Forte looks like and contents of the pack:

Nerisone Forte Ointment and Nerisone Forte Oily Cream are available in aluminium tubes containing 15 g.

Marketing authorisation holder:

Meadow Laboratories Limited
Unit 13, Falcon Business Centre
Ashton Road
Romford
Essex RM3 8UR
United Kingdom

Manufacturer:

Bayer Healthcare Manufacturing S.r.l.
Via E. Schering 21
20090 Segrate (MI)
Italy

This leaflet was last revised in December 2016.

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