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Nerisona	Great Britain (Meadow)	
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MEADOW

Patient information Leaflet

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

1. What Nerisone is and what it is used for

Nerisone 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 is used to treat skin conditions such as eczema, dermatitis and some types of psoriasis, where there is no infection and where milder treatments have not been effective.

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

Nerisone 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 Cream is suitable for weeping skin conditions. It allows secretions from the skin to drain away. Nerisone Cream is also suitable for moist, exposed and hairy areas of skin.

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

Your doctor will prescribe the correct product to treat your specific condition. In this leaflet they are referred to jointly as Nerisone.

2. Before you use Nerisone

Do not use Nerisone if you:

- are **allergic** (hypersensitive) to any of its ingredients (see section 6)
- have rosacea (an inflammatory **skin disease causing facial redness**)
- suffer from **inflammation** around the **mouth** (peri-oral dermatitis)
- suffer from an **eye** disease
- 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 should not be used to treat children under 1 year of age and should not be used to treat **nappy rash**.

Take special care with Nerisone:

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.

- **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 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 or use it for longer than your doctor tells you.

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

Infants and Children

Nerisone must not be used in children less than 1 year of age.

Avoid long term continuous treatment with this medicine. Nerisone 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 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 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 you should use. Generally, each dressing should not be left for more than 24 hours. In some cases your doctor may recommend that 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.

Taking other medicines

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



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development of a baby in pregnant women treated with Nerisone 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 you are breast-feeding Nerisone should not be applied to your breasts.

Driving and using machines

Nerisone has not been shown to have any effect on your ability to drive or operate machinery.

Important information about some of the ingredients of Nerisone

Nerisone Cream contains stearyl alcohol and may cause local skin reactions (e.g. contact dermatitis). It also contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

3. How to use Nerisone

Always use your medication exactly as directed by your doctor. Wash your hands before and after using Nerisone.

Gently spread a **thin layer** of Nerisone 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 your condition improves your doctor may suggest using Nerisone once a day. Do not use Nerisone longer than 4 weeks unless your doctor tells you to.

If used on the face, Nerisone should not be used for more than 5 days and should never be covered with a dressing.

Children over 5 years of age and adolescents

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

If used on the face, Nerisone should not be used for more than 5 days and should never be covered with a dressing.

Children from 1 to 4 years of age

Typical dosage: apply thinly twice a day. Use Nerisone with care and for no longer than 5 days. Do not use dressings to cover the

affected areas during the treatment.

Children under 1 year of age

Nerisone must not be used in children less than 1 year of age.

If accidentally swallowed

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

If you forget to use Nerisone

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 can cause side effects, although not everybody gets them.

Rarely an **allergic reaction** to Nerisone 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, 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 is applied to large areas (10% or more) of the body and used for long periods of time (more than 4 weeks), especially if waterproof dressings are used. The risk of glaucoma is also increased if Nerisone is applied to the skin around the eyes.

Extremely rarely Nerisone 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

Keep out of the reach and sight of children.

Do not use after the expiry date on the pack.

Do not store above 25° C.

6. Further information

What Nerisone contains:

Nerisone Ointment, Nerisone Cream and Nerisone Oily Cream contain 0.1% of the active ingredient diflucortolone valerate.

Inactive ingredients:

Nerisone Ointment: heavy liquid paraffin, white soft paraffin, microcrystalline wax, castor oil (hydrogenated).

Nerisone Cream: polyoxyl-40-stearate [E431], stearyl alcohol, heavy liquid paraffin, white soft paraffin, disodium edetate, carbomer, sodium hydroxide, methyl parahydroxybenzoate [E218], propyl parahydroxybenzoate [E216] and purified water.

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

What Nerisone looks like and contents of the pack:

Nerisone Ointment, Nerisone Cream and Nerisone Oily Cream are available in aluminium tubes containing 30 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

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