SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nerisone® Oily Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100g oily cream contains 0.1g diflucortolone valerate

3. PHARMACEUTICAL FORM

Oily Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the topical treatment of corticoid-responsive dermatoses that are unresponsive to less potent corticosteroids and in the absence of infection.

4.2 Posology and method of administration

Adults: Initially, Nerisone should be applied thinly twice daily. When the condition improves or when longer periods of treatment are required one application daily is appropriate.

Long-term continuous therapy with topical corticosteroids should be avoided, with a usual maximum duration of 4 weeks. If used on the face, courses should be limited to 5 days and occlusion should not be used (see section 4.4).

Children 1-4 years of age: Nerisone should be applied thinly twice daily. It should be used with great care, for short periods and generally only on the advice of a doctor specialising in dermatology. Courses should be limited to 5 days and occlusion should not be used.

Children 5 years of age and over: Initially, Nerisone should be applied thinly twice daily. When the condition improves one application daily is appropriate. Courses should be limited to 1–2 weeks. If used on the face, courses should be limited to 5 days and occlusion should not be used.

Nerisone should not be used in children under 1 year of age.

Elderly: Natural thinning of the skin occurs in the elderly. No special precautions are required, however, when Nerisone is used in this group of patients.

Occlusive dressings: An occlusive dressing may be called for in unusually refractory cases and usually under specialist supervision. If an infection develops under the dressing, occlusive treatment must be terminated.

Nerisone Oily Cream is suitable for skin conditions which are neither weeping nor very dry. Such conditions require a base with balanced proportions of fat and water. Nerisone Oily Cream makes the skin slightly greasy without retaining heat or fluid.

4.3 Contraindications

Rosacea and peri-oral dermatitis.
Acne vulgaris, undiagnosed perianal and genital pruritus, napkin eruptions, viral infections, primary bacterial or fungal infections of the skin.
Secondary infections in the absence of appropriate anti-infective therapy.
Post vaccination skin reactions in the area to be treated.

Nerisone is not suitable for the treatment of ophthalmic conditions.

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Long-term continuous therapy with topical corticosteroids should be avoided, with a usual maximum duration of 4 weeks irrespective of age. Adrenal suppression can occur, even without occlusion. If used on children up to the age of 4 years or on the face, courses should be limited to 5 days and occlusion should not be used.

Nerisone may be applied under an occlusive dressing. However, each dressing should not be left on for more than 24 hours. Although occlusive dressings may be used repeatedly, it should be noted that systemic corticoid absorption is likely to be increased with a consequent increased risk of adrenal suppression. If occlusive treatment is expected to be prolonged, it is advisable to change the dressing every 12 hours.

Nerisone should not be allowed to come into contact with the eyes.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalised pustular psoriasis, and local and systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important in psoriasis.

Exacerbation of skin infections may occur. Infections or secondarily infected dermatoses require additional therapy with antibiotics or

chemotherapeutic agents. This treatment can often be topical, but for heavy infections systemic antibacterial therapy may be necessary. If fungal infections are present, a topically active antimycotic should be applied.

If aggravation of skin irritation develops with the use of Nerisone, treatment should be withdrawn and appropriate therapy installed.

Allergic contact dermatitis due to topical corticosteroids and excipients can occur. In these cases eczema fails to improve or deteriorates with treatment. Corticosteroid hypersensitivity occurs most frequently among patients with stasis dermatitis and leg ulceration. Such an observation should be corroborated with appropriate diagnostic patch testing. The appropriate corticosteroid concentration and the choice of the vehicle is crucial in detecting corticosteroid hypersensitivity in patch tests.

Patients with an allergy to corticosteroids may cross-react to several corticosteroids to which they have not previously been exposed.

After topical application, allergies to cross-reacting systemically applied corticosteroids may occur.

As known from systemic corticoids, glaucoma may also develop by using local corticoids (e.g. after large dosed or extensive application over a prolonged period, occlusive dressing technique or application to the skin around the eyes).

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities in foetal development including cleft palate and intra-uterine growth retardation. There may, therefore, be a very small risk of such effects on the human foetus and, as a general rule, topical preparations containing corticoids should not be applied during the first trimester of pregnancy. In particular, application to large areas of the body or for prolonged periods must be avoided.

Side effects cannot be excluded in neonates whose mothers have been treated extensively or for a prolonged period of time during pregnancy or while lactating (for example, reduced adrenocortical function, when applied during the last weeks of pregnancy).

Nursing mothers should not be treated on the breasts.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Common local adverse reactions reported with Nerisone formulations in clinical studies include burning, pruritus, erythema and irritations.

In common with all other topical corticoids, side-effects may occur when Nerisone is applied to large areas of the body (10% or more) and for long periods of time (more than four weeks), especially if the ointment or an occlusive dressing is being used. There may be local signs such as atrophy of the skin, telangiectasia, striae, acneform changes, perioral dermatitis and hypertrichosis, or systemic corticoid effects caused by absorption. Systemic absorption can produce the features of hypercorticism. Therefore, caution should be exercised when using occlusive dressings, as there is a possibility that natural steroid production may be suppressed.

In rare cases, allergic skin reactions may occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

On the basis of results from acute toxicity studies with both diflucortolone valerate and Nerisone preparations, no acute risk of intoxication is to be expected either after a single dermal application of an overdose (application over a large area under conditions favouring resorption) or even after inadvertent oral intake of a whole tube.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Diflucortolone valerate is a topically acting fluoridated corticosteroid which suppresses inflammation in inflammatory and allergic skin conditions and alleviates the subjective complaints such as itching, burning and pain.

Capillary dilatation, intercellular oedema and tissue infiltration regress; capillary proliferation is suppressed. This leads to fading of inflamed skin surfaces.

5.2. Pharmacokinetic Properties

In order to exert its antiproliferative and anti-inflammatory effects, diflucortolone valerate has to diffuse from the preparation into the living epidermis and into the upper dermis. *In vitro* penetration studies showed that diflucortolone valerate penetrates human skin rapidly. After application to damaged skin - as a model for diseased skin - the local corticosteroid levels were distinctly higher than in the intact skin.

Once in the skin diflucortolone valerate is partly hydrolysed into the similarly effective diflucortolone. Part of the corticosteroid applied to the skin is percutaneously absorbed, distributed into organs and tissues, metabolised and finally excreted. The extent of percutaneous absorption and the resulting systemic load depend on a series of factors: the vehicle, the exposure conditions (skin area dose, treatment area, duration of treatment), condition of treatment (open/occlusive), the status of the penetration barrier and the localisation of the treated area on the body.

After application of the radiolabelled ointment onto an intact and a “stripped” area of skin on the back of 3 volunteers, 0.7% of the dose was percutaneously absorbed during a 7 hour exposure period.

Following percutaneous absorption diflucortolone valerate is hydrolysed very rapidly into diflucortolone and the respective fatty acid. 11-keto-diflucortolone and two further metabolites have been found in the plasma in addition to diflucortolone. Diflucortolone is eliminated from the plasma with a half-life of approximately 4-5 hours, all metabolites together with a half-life of approximately 9 hours (results after i.v. administration). The metabolites are excreted with urine and faeces in a ratio of 75:25.

5.3. Pre-clinical Safety Data

There are no preclinical safety data which could be of relevance to the prescriber and which are not already included in other relevant sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

White beeswax
Heavy liquid paraffin

White soft paraffin
Dehymuls E
Purified water

6.2. Incompatibilities

None stated.

6.3 Shelf life

5 years

After first opening the container: 3 months

6.4. Special Precautions for Storage

None.

6.5. Nature and Contents of Container

Aluminium tube containing 30g oily cream.

6.6. Instructions for Use/Handling

Keep out of reach of children.

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 19115/0005

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

15 August 2002

10 DATE OF REVISION OF THE TEXT

15/11/2016