SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nerisone® Forte Ointment.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100g ointment contains 0.3g diflucortolone valerate.

3. PHARMACEUTICAL FORM

Fatty ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For short term topical treatment of severe and recalcitrant corticoid-responsive dermatoses that are unresponsive to less potent corticosteroids and in the absence of infection. These include neurodermatitis (endogenous eczema, atopic dermatitis), lichen planus, discoid lupus erythematosus, severe chronic eczema and psoriasis. Nerisone Forte should not be applied to large areas of the body (more than 10%) in psoriasis (see section 4.4).

4.2 Posology and method of administration

Adults: Initially, Nerisone Forte should be applied thinly twice daily. When the condition improves, one application daily is appropriate. It is intended for short-term use of 1-2 weeks with a usual maximum duration of 2 weeks. In view of the high efficacy and potency of Nerisone Forte, no more than 60 g a week should be applied.

Children of 5 years of age and over: Initially, Nerisone Forte should be applied thinly twice daily. When the condition improves, one application daily is appropriate. 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 1-2 weeks.

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

Once the clinical picture has improved, the patient should be changed from Nerisone Forte to Nerisone if further therapy is necessary (see section 4.4).

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

Nerisone Forte Ointment is suitable for very dry skin conditions. It has an anhydrous fatty base. Its occlusive effect promotes the healing process.

4.3. Contraindications

- 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 Forte is not suitable for the treatment of ophthalmic conditions.

Infants and children up to the age of 4 years must not be treated with Nerisone Forte.

Nerisone Forte Ointment should never be applied to the face.

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, irrespective of age. Adrenal suppression can occur, even without occlusion.

In view of the high efficacy and potency of Nerisone Forte it is suggested that treatment for one or two weeks should generally be sufficient to obtain control of even the most refractory lesion, after which a change to Nerisone can usually be made if further therapy is necessary.

Since prolonged therapy with potent topical corticosteroids may cause local atrophic changes such as striae, thinning, hypertrichosis and telangiectasia, particularly in skin folds and where occlusive dressings are used, it is recommended that the progress of patients under treatment for more than one week with Nerisone Forte be reviewed weekly, and that repeat prescriptions be written only when the prescribing physician has seen the patient again.

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.

Since absorption is increased with the use of occlusive dressings, these should not be left on for more than 24 hours. If secondary infection occurs during treatment, the use of occlusive dressings should be stopped until

the infection has been eliminated, and appropriate treatment of the infection should be instituted if it persists.

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. Interactions with other medicinal products and other forms of interaction

None known.

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

Not applicable.

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 potent topical corticosteroids, there may be local signs such as atrophy of the skin, striae, thinning, acneform changes, hypertrichosis and systemic effects of the corticoid due to absorption and telangiectasia, particularly in skin folds and where occlusive dressings are used. Side-effects may occur when Nerisone Forte is applied to large areas of the body (10% or more) and for long periods of time (more than 10 days). Systemic absorption can produce the features of hypercorticism.

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 Forte 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. A proportion 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. Preclinical 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

Liquid paraffin
White soft paraffin
Lunacera M (microcrystalline wax)
Castor oil, hydrogenated

6.2. Incompatibilities

None known.

6.3. Shelf life

5 years.

6.4. Special precautions for storage

None.

6.5. Nature and contents of container

Aluminium tube containing 15g ointment.

6.6 Special precautions for disposal

Keep out of reach of children.

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL: 19115/0003.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st February 2003.

10 DATE OF REVISION OF THE TEXT

14/04/2015