Important information. Please read carefully.

Uniflex-N™

Cream

COMPOSITION

Betamethasone 17-valerate equivalent to Betamethasone 0.1% w/w with Neomycin Sulphate 0.5% w/w equivalent to potency not less than 600µg Neomycin per mg.

PHARMACODYNAMICS

Betamethasone 17-Valerate is a synthetic glucocorticoid whose principal actions are gluconeogenesis, glycogen deposition, protein and calcium metabolism, inhibition of corticotrophin secretion and anti-inflammatory activity. Its effectiveness in topical applications is primarily due to its anti-inflammatory and antipruritic actions.

Neomycin is a broad spectrum antibiotic which acts by inhibition of protein synthesis. It is bactericidal and effective against staphylococci and a wide range of Gram-negative bacteria including *Escherichia coli*, *Klebsiella*, *Haemophilus influenzae*, *Salmonella* and *Shigella*.

PHARMACOKINETICS

Betamethasone is absorbed through the skin, particularly in denuded areas. Its penetration through the skin can be increased by means of an occlusive dressing. The absorbed betamethasone is metabolised in the liver and excreted in the urine.

Neomycin sulphate may be absorbed through wounds and inflamed skin. Once absorbed, it is rapidly excreted by the kidneys in the active form.

INDICATIONS

Uniflex-N Cream is indicated for the relief of corticosteroid-responsive inflammatory dermatoses, especially when secondary bacterial infection is present or likely to be present. It is indicated for the treatment of eczema, psoriasis, lichen planus, seborrheic dermatitis, intertrigo, contact sensitivity reactions, discoid lupus erythematosus, generalized erythroderma.

Uniflex-N can be used for the relief of insect bites and stings.

DOSAGE AND ADMINISTRATION

For external use only. Apply a thin film of **Uniflex-N** Cream to the affected areas one to three times a day until improvement occurs. It is often effective to maintain improvement by just two or fewer applications a day.

CONTRAINDICATIONS

Uniflex-N Cream should not be used for acne, rosacea or on areas around the mouth; viral infections such as herpes simplex (cold sore), chicken pox; fungal or bacterial infections. **Uniflex-N** is contraindicated in patients with a history of sensitivity to any of its components.

WARNINGS AND PRECAUTIONS

If irritation develops with the use of **Uniflex-N**, treatment should be discontinued and appropriate therapy instituted.

Prolonged topical therapy should be avoided where possible. Any of the side effects reported following systemic use of corticosteroids including adrenal suppression, may also occur following their topical use, especially in children and infants. Systemic absorption will be increased if extensive body surfaces are treated or if occlusive dressing is used.

Although topical steroids have not been reported to have adverse effect on human pregnancy, their safe use in pregnant women has not been absolutely established. In laboratory animals, topical administration of steroids has been associated with foetal deformities. Therefore, corticosteroid should not be used in large amounts or for prolonged periods in pregnant women.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

DRUG INTERACTIONS

Topical application of **Uniflex-N** is not likely to produce significant drug interactions. Systemically, neomycin may enhance the anticoagulant effects of warfarin and nicoumalone. Its ototoxicity may be increased by ethacrynic acid and frusemide. Concurrent use of barbiturates, phenytoin, or rifampicin may enhance the metabolism and decrease the effect of corticosteroids.

SIDE EFFECTS

Uniflex-N is usually well tolerated, but adverse reactions like irritation, dryness, allergic contact dermatitis, blurred vision may sometime occur. If hypersensitivity occurs, treatment should be discontinued immediately.

OVERDOSAGE AND TREATMENT

Neomycin is non-toxic when applied locally. Accidental ingestion of excessive doses may cause deafness, renal damage, nausea, vomiting and diarrhea. Overdosage of corticosteroids may cause adrenal atrophy and show signs of Cushing's syndrome, with moon face, striae, acne and buffalo hump. There is no specific antidote for overdosage due to accidental oral ingestion of **Uniflex-N** cream. The neuromuscular blocking activity of neomycin may be reversed by neostigmine or a calcium salt.

SHELF LIFE
The expiry date is indicated on the packaging.

PRESENTATION
White, homogeneous water miscible cream in tubes of 15g.

STORAGE
Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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Manufacturer and Product Registration Holder
Xepa-Soul Pattinson (Malaysia) Sdn Bhd
1 -5 Cheng Industrial Estate, 75250 Melaka, Malaysia