Important information. Please read carefully.

Uniflex™ Cream

0.1%, 0.05% and 0.025%

COMPOSITION

Uniflex Cream 0.1%

Contains Betamethasone 17-valerate equivalent to Betamethasone 0.1% w/w in a non-greasy water miscible cream. Chlorocresol 0. 15 % w/w as preservative.

Uniflex Cream 0.05%

Contains Betamethasone 17-valerate equivalent to Betamethasone 0.05% w/w in a non-greasy water miscible cream. Chlorocresol 0. 15 % w/w as preservative.

Uniflex Cream 0.025%

Contains Betamethasone 17-valerate equivalent to Betamethasone 0.025% w/w in a non-greasy water miscible cream. Chlorocresol 0. 15 % w/w as preservative.

PHARMACODYNAMICS

Betamethasone 17-valerate is a potent synthetic corticosteroid with anti-inflammatory and antipruritic actions.

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 metabolized in the liver and excreted in the urine.

INDICATIONS

For the relief of inflammatory manifestations of corticosteroid-responsive dermatoses such as in eczema, infantile eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, seborrheic dermatitis, neurodermatitis, some form of psoriasis and intertrigo.

DOSAGE AND ADMINISTRATION

For external use only. Apply sparingly onto the affected area 2 to 3 times a day. When a favourable response is obtained, reduce application gradually and eventually discontinue.

CONTRAINDICATIONS

Unless under medical supervision, **Uniflex** should not be used for rosacea or on areas around the mouth. **Uniflex** should not be used for acne, viral skin infections e.g. herpes simplex (cold sores) and chicken pox; fungal infections e.g. candidiasis; bacterial infections; in patients with a history of sensitivity to any of its components.

Do not use in children under one year of age, including dermatitis and napkin eruptions.

WARNINGS AND PRECAUTIONS

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

Prolonged 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 and should not be in large amounts or for prolonged periods in pregnant women.

Avoid prolonged use or over large areas of the body particularly in areas where the skin is thinner or with occlusive dressing present. Unless under medical supervision, do not use on the face. Do not use on eyes, in the ano-genital region and on broken or infected skin including cold sores, acne and athletes' foot. Use in children and babies may increase risk of systemic absorption which may lead to side effects such as adrenal suppression. Indiscriminate use in pruritus may cause a rebound exacerbation of the condition and may occur when treatment is stopped.

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** is not likely to produce significant drug interactions. Concurrent use of barbiturates, phenytoin, or rifampicin may enhance the metabolism and decrease the effect of corticosteroids.

SIDE EFFECTS

Uniflex is generally well tolerated when used for short durations and over small areas. If application of more than 100g per week is used, betamethasone ester, being a potent corticosteroid, is likely to produce the severe side-effects associated with steroid use such as pituitary-adrenal-axis suppression.

As with other topical corticosteroids, prolonged use of large amount or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercorticism and suppression of HPA axis. These effects are likely to occur in infants and children, and if occlusive dressings is used.

Local side-effects may include spread of local infections, thinning of the skin, irreversible striae atrophicae, increased hair growth, acne, mild depigmentation and growth of vellus hair and perioral dermatitis in young women. Blurred vision can also occur.

OVERDOSAGE AND TREATMENT

Overdosage of corticosteroids may cause adrenal atrophy and show signs of Cushing's syndrome, with moon face, striae, acne and buffalo hump.

Treatment is symptomatic. When possible, the drug should be slowly withdrawn.

SHELF LIFE

The expiry date is indicated on the packaging.

PRESENTATION

White, odourless, water-miscible cream in tubes of 15g.

STORAGE
Uniflex Cream 0.1%
Store below 30°C. Protect from light.

Uniflex Cream 0.05% and Uniflex Cream 0.025%
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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Manufactured and Product Registration Holder
Xepa-Soul Pattinson (Malaysia) Sdn Bhd
1 -5 Cheng Industrial Estate, 75250 Melaka, Malaysia

Product Registrant
Apex Pharma Marketing Pte Ltd
4 Loyang Way 1, #02-00 Singapore 508708