

Important information. Please read carefully.

Xeralix Ointment

COMPOSITION

Contains Betamethasone 0.05% w/w (as Betamethasone Dipropionate 0.064% w/w) and Salicylic Acid 3% w/w.

PHARMACODYNAMICS

Betamethasone dipropionate is a glucocorticoid exhibiting the general properties of corticosteroids while salicylic acid is with keratolytic properties.

Salicylic acid is applied topically in the treatment of hyperkeratotic and scaling conditions where its keratolytic action facilitates penetration of the corticosteroid.

In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

PHARMACOKINETICS

Salicylic acid exerts only local action after topical application.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.

Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolized primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

INDICATIONS

XERALIX Ointment is indicated for the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid responsive dermatoses such as: psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including

nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

DOSAGE AND ADMINISTRATION

For topical use only.

To be applied twice daily, in the morning and at night.

A thin film of Xeralix Ointment should be applied to cover completely the affected area.

For some patients, adequate maintenance therapy may be achieved with less frequent application.

If used in children or on the face courses should be limited to five days.

CONTRAINDICATIONS

Rosacea, acne, perioral dermatitis, perianal and genital pruritis.

Hypersensitivity to any of the ingredients of the Xeralix ointment contraindicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella.

Should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

WARNINGS AND PRECAUTIONS

- Occlusion must not be used, since under these circumstances the keratolytic action of salicylic acid may lead to enhanced absorption of the steroid.
- Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in children.
- Topical corticosteroids may be hazardous in psoriasis due to rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.
- Not for ophthalmic use. Avoid contact with the eyes and mucous membranes.
- The systemic absorption of betamethasone dipropionate and salicylic acid may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children.
- If skin irritation or sensitization, and excessive dryness develops, the treatment should be discontinued. In the presence of an infection, appropriate therapy has to be indicated.

- Any side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.
- Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances 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.
- Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.
- Not to smoke or go near naked flames while using this product due to the risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.
- Individual allergic to aspirin/other NSAID should avoid using this product.

DRUG INTERACTIONS

No known data.

PREGNANCY AND LACTATION

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

SIDE EFFECTS

Betamethasone preparation containing salicylic acid is generally well tolerated.

Side effects are rare.

Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis are the known adverse reactions with the use of topical corticosteroids. Vision blurred has been reported with corticosteroid use.

Maceration of the skin, secondary infection, skin atrophy, striae and miliaria may occur more frequently with the use of occlusive dressings.

Prolonged use of salicylic acid preparations may cause dermatitis.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.

Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

Excessive prolonged use may result in symptoms of salicyclism. Treatment is symptomatic. Measures should be taken to rid the body rapidly of salicylate. Administer oral sodium bicarbonate to alkalinise the urine and force diuresis.

The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

STORAGE CONDITION

Store below 30°C.

SHELF LIFE

The expiry date is indicated on the packaging.

PRODUCT DESCRIPTION, DOSAGE FORM AND PACKAGING AVAILABLE

White to off-white, smooth, homogeneous ointment.
Available in pack size of 15g.

For further information, please consult your physician or pharmacist.

Revision Date: 08-August-2022

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