

SYNALAR

Fluocinolone Acetonide 0.025% w/w

Presentation

SYNALAR is available as a white water-miscible cream, a greasy ointment and a clear water-miscible gel each containing Fluocinolone Acetonide Ph Eur 0.025% w/w.

Uses

Actions

Fluocinolone acetonide is a synthetic anti-inflammatory corticosteroid. Its mechanisms of action are related to vasoconstriction and suppression of membrane permeability, mitotic activity, the immune response and release of inflammatory mediators.

Pharmacokinetics

The extent of percutaneous absorption of fluocinolone acetonide is determined by many factors including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings. Following absorption, fluocinolone acetonide is metabolised primarily in the liver and excreted by the kidneys.

Indications

SYNALAR cream and ointment are indicated for the management of a wide variety of inflammatory, pruritic and allergic disorders of the skin including eczema, dermatitis, intertrigo, prurigo, lichen planus, psoriasis and discoid lupus erythematosus.

The cream is particularly suitable for moist or weeping surfaces and for flexures of the body and the ointment is suitable for dry, scaly lesions.

SYNALAR Gel is indicated for the management of seborrhoea, seborrhoeic dermatitis and psoriasis of the scalp and other hairy regions of the body. It may also be applied satisfactorily to the inflammatory dermatoses on other parts of the body.

Dosage and Administration

Adults and Children

A small quantity is applied lightly to the affected area up to three times a day and massaged gently and thoroughly into the skin.

Contraindications

SYNALAR is contraindicated in primary infections of the skin caused by bacteria, fungi or viruses and in rosacea, acne, and perioral dermatitis, anogenital pruritus and napkin rash.

Warnings and Precautions

Where there is an infection associated with an inflammatory skin condition SYNALAR preparations should only be administered if adequate anti-infective cover is given. The use of topical steroids on infected lesions, without the addition of appropriate anti-infective therapy, can result in the spread of opportunist infections.

Long-term continuous topical steroid therapy can produce atrophic skin changes and dilation of the superficial blood vessels particularly when occlusive dressings are used or where skin folds are involved. Prolonged use of topical steroids or treatment of extensive areas, even without occlusion, can result in sufficient absorption of the steroid to produce the features of hypercorticism and underlying adrenal suppression, especially in infants and children.

SYNALAR with rare exceptions should not be applied to the face. If it is applied to the face, this should not be for prolonged periods. The eyes should be avoided.

It is recommended that treatment of children should not normally be extended beyond five days and occlusion should not be used. SYNALAR preparations are not advised in the treatment of dermatoses in children under one year of age.

Topical steroids should not normally be used to treat widespread plaque psoriasis.

When using topical steroids to treat psoriasis there are risks both of rebound relapse following the development of tolerance, and of generalised pustular psoriasis. Impairment of the barrier function of the skin may lead to local and systemic toxicity. Careful patient supervision is important.

Treatment with topical steroids should be discontinued if unfavourable reactions are observed.

Pregnancy

Topical administration of steroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to humans has not been established. When topical steroid treatment is considered necessary during pregnancy, both the amount applied and the length of treatment should be minimised.

Lactation

Topical steroids should not be applied to the breasts prior to nursing. When topical steroid treatment is considered necessary for other parts of the body, both the amount applied and the length of treatment should be minimised.

Effect on ability to drive or operate machinery

No precautions are necessary.

Adverse Effects

Irritation at the site of application may occur infrequently. Hypersensitivity reactions have been reported rarely.

Interactions

Nil.

Overdosage

Toxic effects are not likely to occur following accidental ingestion of the contents of a tube. If greater quantities are ingested and toxicity develops, symptomatic treatment should be given.

Pharmaceutical Precautions

Store below 25°C.

Medicine Classification

Prescription Medicine

Package Quantities

SYNALAR Gel, cream and ointment are available in 30 gram tubes.

Name and Address

AFT Pharmaceuticals Ltd
P O Box 33-203
Takapuna
Auckland
Ph (09) 488 0232 Fax (09) 488 0.234
E:mail customer.service@aftpharm.com

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