PACKAGE INSERT

Axcel®
FUNGICORT
CREAM

MAL19985532AZ

COMPOSITION:

Miconazole Nitrate (micronised)	2% w/w
Hydrocortisone (micronised)	1% w/w

Chlorocresol 0.1% w/w as preservative.

PRESENTATION:
A white, water-miscible cream.

INDICATIONS:
Treatment of fungal infections of the skin including candidiasis, tinea, and pityriasis versicolor, where inflammation of the skin is also present.

PHARMACOLOGY:
Mechanism of Action:
Miconazole is an imidazole antifungal agent which interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi. It has a broad antifungal spectrum; it is fungicidal to *Trichophyton*, *Epidermophytes*, *Microsporum*, *Candida*, *Cryptococcus* and *Aspergillus*. Hydrocortisone is a glucocorticoid whose principal pharmacological actions include gluconeogenesis, glycogen deposition, and protein, lipid, and calcium metabolism, together with anti-inflammatory activity. It is effective topically because of its anti-inflammatory, antipruritic and vasoconstrictive actions.

Pharmacokinetics:
There is little absorption of miconazole nitrate through skin or mucous membranes when it is applied topically. If taken orally, miconazole is incompletely absorbed from the gastrointestinal tract. It is metabolised in the liver to inactive metabolites. From 10 to 20% of an oral dose is excreted in the urine as metabolites. About 50% of an oral dose may be excreted mainly unchanged in the faeces. Hydrocortisone is readily absorbed from the gastrointestinal tract and peak blood concentrations are attained in about an hour. It is also absorbed through the skin, particularly under an occlusive dressing or in denuded areas. Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

DIRECTION FOR USE:
For external use only.

Apply 1 cm of the cream, or more, onto the lesion according to its size, once to twice a day. Rub the cream gently with your finger until it has been completely absorbed by the skin. Treatment should be continued without interruption until the lesion has completely disappeared.

CONTRAINDICATION:
Tuberculosis of the skin, chicken-pox, vaccinia, herpes simplex, known hypersensitivity to any component of the cream.

PRECAUTION:
When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amount to cause systemic effects. Avoid prolonged use in infants and children, and on the face. In patients on warfarin, caution should be exercised and the anticoagulant effect should be monitored.

Use in Pregnancy and Lactation:
The safety of the use of topical steroid preparations during pregnancy has not been fully established. Therefore, they should not be used extensively on pregnant patients, in large amounts or for prolonged periods of time.

SIDE EFFECTS:
Local irritation and sensitivity reactions may occur when miconazole nitrate is used topically; contact dermatitis has been reported. Application of corticosteroids to the skin has led to loss of skin collagen and subcutaneous atrophy; local hypopigmentation of deeply pigmented skins has been reported following topical application of potent corticosteroids.

DRUG INTERACTIONS:
The combination of amphotericin and miconazole appears less effective *in vitro* and *in vivo* against *Candida albicans* than either drug alone. Rifampicin generally reduces the activity of corticosteroids. Miconazole administered systemically is known to inhibit CYP2C9 enzyme system. Due to the limited systemic availability after topical application, clinically relevant interactions occur very rarely. In patients on warfarin which is subjected to metabolism by CYP2C9, caution should be exercised and the anticoagulant effect should be monitored.

OVERDOSAGE:
Prolonged use of topical corticosteroids to large or extensive areas, especially with occlusive dressing, may lead to systemic side-effects, which result from excessive action on electrolyte balance, excessive action on other aspects of metabolism including gluconeogenesis, the action on tissue repair and healing, and an inhibitory effect on the secretion of corticotrophin by the anterior lobe of the pituitary gland. Disturbance of electrolyte balance is manifest in the retention of sodium and water, with oedema and hypertension, and in the increased excretion of potassium with the possibility of hypokalemic

Front Page

alkalosis. Other excessive metabolic effects lead to mobilisation of calcium and phosphorus, with osteoporosis and spontaneous fractures, nitrogen depletion, and hyperglycaemia with precipitation of the diabetic state. Patients may be more susceptible to infections including tuberculosis and viral infections. Large doses of corticosteroids may also produce Cushingoid symptoms typical of hyperactivity of the adrenal cortex, with moon-face, sometimes with hirsutism, buffalo hump, flushing, increased bruising, striae, and acne, and sometimes leading to a fully developed Cushing's syndrome. If administration is discontinued these symptoms are usually reversed, but sudden cessation is dangerous.

TREATMENT FOR OVERDOSAGE:
Treatment of systemic side-effects due to prolonged use of hydrocortisone or use under occlusive dressings over large areas are symptomatic, with the drug slowly withdrawn.

STORAGE:
Keep container well closed. Store below 30^{O}C.
Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

PACK QUANTITIES:
Available in aluminium tube of 5gm and 15gm .

Further information can be obtained from pharmacist, physician or the manufacturer.

Product Registration Holder & Manufactured By :
Kotra Pharma (M) Sdn. Bhd.
No.1, 2 & 3, Jalan TTC 12, (90082-V)
Cheng Industrial Estate,
75250 Melaka, Malaysia.

REGN 131022 Date of revision: 13/10/22

Back Page