RESOLVE PLUS 1.0

Hydrocortisone, miconazole nitrate

PRODUCT INFORMATION

NAME OF MEDICINE

Resolve Plus 1.0.

DESCRIPTION

Resolve Plus 1.0 is a white, glossy cream containing hydrocortisone 1% w/w and miconazole nitrate 2% w/w with phenethyl alcohol as preservative. It contains the inactives: water, 1,3-butylene glycol, cetostearyl alcohol, citric acid – anhydrous, dimethicone 350, disodium edetate, self emulsifying glyceryl monostearate, light liquid paraffin, peg-40 stearate, povidone, sodium phosphate – dibasic anhydrous and xanthan gum.

PHARMACOLOGY

Resolve Plus 1.0 is a broad-spectrum anti-fungal and anti-inflammatory cream containing hydrocortisone 1% w/w and miconazole nitrate 2 % w/w as the active ingredients. Hydrocortisone has anti-inflammatory, anti-eczematous, anti-allergic and anti-pruritic properties. Miconazole is particularly active against species of medical interest such as *Candida, Trichophyton, Epidermophyton, Microsporum, Pityrosporum*, other yeast-like fungi and dermatophytes as well as Gram positive bacteria such as *Streptococcus pyogenes* and *Staphylococcus aureus*.

Pharmacodynamics

Miconazole nitrate is an antifungal agent and acts by altering the permeability of the cell membrane in sensitive fungi.

Hydrocortisone is an anti-inflammatory agent the topical application of which often produces dramatic suppression of skin diseases in which inflammation or pruritus are prominent features.

Pharmacokinetics

The absorption of miconazole is not significant when applied topically.

Hydrocortisone is metabolised in the liver most likely by reduction of the 5,6 double bond and the C3 and C20 keto groups. The resultant hydroxy derivatives are then conjugated with glucuronic acid. Cortisone, an 11-keto-steroid is formed from hydrocortisone; the 11-keto-steroids are then reduced and conjugated to yield glucuronide metabolites. A small percentage of hydrocortisone is converted to the 17-keto-steroid. The C21 hydroxyl group is conjugated with sulphate.

When radioactive-carbon, ring-labelled steroids are injected intravenously in man, most of the radioisotope is recovered in the urine within 72 hours. Neither biliary nor faecal excretion is of any quantitative importance in man. It has been estimated that the liver metabolises at least 70% of the hydrocortisone secreted.

Hydrocortisone is absorbed through the skin allowing penetration to the deeper layers. The extent of absorption is greater for inflamed skin and other skin conditions such as eczema and psoriasis. Absorption is also greater in areas such as the ear, scrotum, axillae, face and scalp. Absorption is aided by occlusive dressings due to the resulting hydration of the skin. However, occlusive dressings may not be appropriate as the resulting warm and moist conditions provide a favourable environment for microbial growth. Once absorbed, the pharmacokinetics are similar to systemic steroids.

INDICATIONS

Inflamed or itchy fungal skin infections such as:

- tinea;
- thrush;
- seborrhoeic dermatitis;
- thrush infected napkin rash;
- intertriginous eruptions;

- inflamed fungal infections where bacterial infection may be present.

For conditions without a significant inflammatory component an antifungal agent without hydrocortisone, such as Resolve Cream, should be used.

DOSAGE AND ADMINISTRATION

A small amount should be gently rubbed into the infected skin and surrounding area 2 times daily. Resolve Plus 1.0 should be used until the inflammation has subsided. Once inflammation has subsided continue treatment with an antifungal agent without hydrocortisone, such as Resolve Cream until symptoms disappear. Continue treatment with the antifungal agent without hydrocortisone for 14 days after symptoms disappear.

CONTRAINDICATIONS

- Do not use in the eye.
- Acne.
- Hypersensitivity to miconazole nitrate, hydrocortisone or phenethyl alcohol or any other ingredient;
- Herpes and other viral diseases of the skin (such as chicken pox), perioral dermatitis and ulcerative skin conditions.

WARNINGS AND PRECAUTIONS

For external use only.

Avoid contact with eyes.

If hypersensitivity develops, discontinue use.

Long term corticosteroid use may increase the risk of hypothalamic-pituitary axis suppression, especially under occlusion. Use for longer than 4 weeks can cause atrophic striae, prolonged use on flexures and in intertriginous areas is undesirable.

If an associated infection develops during the use of Resolve Plus 1.0 and does not respond to therapy, its use should be discontinued until the infection is adequately controlled.

This preparation is not recommended for use in children under 2 years of age except on the advice of a doctor.

The risk of systemic absorption, and hence systemic toxicity, is greater in children due to the higher permeation properties of the skin and a larger skin surface to body weight ratio than adults.

PREGNANCY AND LACTATION

Hydrocortisone and miconazole nitrate are Category A drugs as defined in ‘Medicines in Pregnancy’ approved by the Australian Drug Evaluation Committee. Category A drugs are those which have been taken by a large number of pregnant women and women of child-bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

It is not known whether corticosteroids and miconazole are distributed into breast milk following topical application. However, Resolve Plus 1.0 should be used with caution in breastfeeding mothers. If application to the breasts is required, then the product should be applied immediately after breastfeeding.

ADVERSE EFFECTS

After the application of Resolve Plus 1.0 a slight stinging sensation may occasionally be noticed. This transient symptom is most likely to disappear after several applications. Other side effects (especially under occlusion) may include itching, redness, allergy, acneform eruptions and skin atrophy (thinning of the skin).

POISONS SCHEDULE

S3

PACKAGE QUANTITIES

15 g and 30 g tubes.

MANUFACTURER

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