New Zealand Data Sheet

1. PRODUCT NAME

Resolve® Plus 1.0

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Resolve Plus 1.0% Cream (1% w/w hydrocortisone, 2% w/w miconazole)

Excipient(s) with known effect

Resolve Plus 1.0% Cream contains cetostearyl alcohol, phenethyl alcohol.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A white glossy topical cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Inflamed or itchy fungal skin infections such as:

- inflamed or itchy tinea;
- thrush;
- seborrhoeic dermatitis;
- otitis externa;
- thrush infected napkin rash;
- intertriginous eruptions;
- inflamed fungal infections where bacterial infection may be present

4.2. Dose and method of administration

A small amount should be applied to the infected skin and surrounding area ensuring complete coverage.

The dose should be applied twice daily until the infection and inflammation has disappeared. Treatment should be continued for one week after condition clears.

4.3. Contraindications

- Hypersensitivity to miconazole nitrate, hydrocortisone or phenethyl alcohol or any other ingredient in the product.

- Herpes and other viral diseases of the skin (vaccinia, small pox, chicken pox), perioral dermatitis and tuberculous, syphilitic skin disorders or ulcerative skin conditions.

4.4. Special warnings and precautions for use

For external use only.

Avoid contact with eyes.

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.

Visual disturbance

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.

Paediatric population

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 ration than adults.

4.5. Interaction with other medicines and other forms of interaction

None known.

4.6. Fertility, pregnancy and lactation

Pregnancy

Category A: Drugs 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.

Breast-feeding

It is not known whether sufficient absorption of topical hydrocortisone or miconazole takes place to be excreted in breast milk. The potential benefits should be weighed against possible hazards to the breastfeeding infant.

Fertility

No data available.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

After the application of Resolve Plus 1.0% Cream 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).
Rarely, local sensitivity may occur requiring discontinuation of treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions https://nzphvc.otago.ac.nz/reporting/

4.9. Overdose

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives, combinations, ATC code: D01AC20.

Resolve Plus 1.0% Cream 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.

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

Hydrocortisone has anti-inflammatory, anti-eczematous, anti-allergic and anti-pruritic properties. Topical application of hydrocortisone often produces dramatic suppression of skin diseases in which inflammation or pruritus are prominent features.

5.2. Pharmacokinetic properties

The absorption of miconazole is not significant when applied topically.

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.

Hydrocortisone is metabolised in the liver most likely by reduction of the 5,6 double bond and the C_3 and C_{20} keto groups. The resultant hydroxy derivatives are then conjugated with glucuronic acid. Cortisone, an 11-keto-steroid is formed from hydrocortisone; the 11-ketosteroids 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.

5.3. Preclinical safety data

No specific data available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Resolve Plus 1.0% Cream contains: 1,3-butylene glycol, cetostearyl alcohol, citric acid, disbasic sodium phosphate, dimeticone, disodium edetate dihydrate, glyceryl monostearate, light liquid paraffin, PEG-40 stearate, phenethyl alcohol, povidone, purified water and xanthan gum.

6.2. Incompatibilities

None known.

6.3. Shelf life

30 months.

6.4. Special precautions for storage

Stored at or below 25°C.

6.5. Nature and contents of container

Tube, laminated, in 10g, 15g and 30g.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Any unused medicinal products or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Pharmacist Only Medicine.

8. SPONSOR

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand
Phone: (09) 835 0660

9. DATE OF FIRST APPROVAL

1 April 1999

10. DATE OF REVISION OF THE TEXT

30 July 2018

Summary table of changes

Section Changed	Summary of new information
All	SPC format
4.4	Added precaution regarding Visual disturbance, as per Medsafe request
4.4, 4.8, 5.1, 5.2	Sections added to harmonise with Resolve Plus 0.5 data sheet