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;
- 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 Tinea Cream, should be used.

4.2. Dose and method of administration

A small amount should be gently rubbed into the infected skin and surrounding area ensuring complete coverage.

The dose should be applied twice daily until the infection and inflammation has disappeared. Once inflammation has subsided continue with an antifungal agent without hydrocortisone, such as Resolve Tinea Cream, until symptoms disappear. Continue treatment with the antifungal agent without hydrocortisone for 14 days after symptoms disappear.

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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 (such as chicken pox), perioral dermatitis and tuberculous, syphilitic skin disorders or ulcerative skin conditions.
- Acne.
- Do not use in the eye.

4.4. Special warnings and precautions for use

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.

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

This preparation is not recommended for use in children under 2 years of age.

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

Fertility

No data available.

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 corticosteroids and miconazole are distributed into breast milk following topical application. However, Resolve Plus cream should be used with caution in breastfeeding mothers.

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, acneiform eruptions and skin atrophy (thinning of the skin).

Rarely, local sensitivity may occur requiring discontinuation of treatment.

Table 1: Adverse drug reactions in patients treated with miconazole and hydrocortisone cream

System organ class	**Adverse drug reactions**	
	Frequency category	
	Uncommon (≥ 1/1,000 to < 1/100)	Not known.
Immune system disorders	-	Anaphylactic reaction, hypersensitivity
Eye disorders	-	Vision, blurred, see section 4.4
Skin and subcutaneous tissue disorders	Skin irritation, urticarial, pruritus	Angioedema, rash, contact dermatitis, erythema, skin inflammation, application site reaction
General disorders and administration site conditions	Irritability	

General disorders and administration site conditions

"Rebound effect", see section 4.2.

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

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.

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*.

5.1. Pharmacodynamic properties

Mechanism of action

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

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

Absorption

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 the 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 dressing 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.

Metabolism

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-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.

Excretion

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, Macrogol stearate 2000, 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

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9. DATE OF FIRST APPROVAL

1 April 1999

10. DATE OF REVISION OF THE TEXT

24 February 2022

Summary table of changes

Section Changed	Summary of new information
4.1	Editorial Updates
4.2	Addition of a rebound note as per Medsafe request
4.3	Editorial Updates to align with Reference Product Information
4.4	Added precaution regarding discontinuation of product if an associated infection develops during the use of Resolve Plus 1.0 which does not respond to therapy. Editorial Updates
4.6	Editorial Updates in breast-feeding section.
4.8	Added Table 1 in line with Reference Product Information.
5.1	Added Mechanism of Action.
5.2	Added headings.
6.1	Amended PEG-40 stearate to Macrogol stearate 2000 in line with Medsafe TPDR information