

Homecare® Fungizap® Cream 1% w/w

1 NAME OF THE MEDICINAL PRODUCT

Homecare Fungizap® Cream 1% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 10mg clotrimazole.

Preservative(s):

Phenoxyethanol & Ethylhexylglycerin.....10mg

3 PHARMACEUTICAL FORM

A white to slightly yellowish cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

To treat fungal skin infections such as athlete's foot, white spots, ringworm, fungal infection of the tissues adjacent to the nails, fungal infection of the skin folds and erythrasma (skin redness / irritation).

4.2 Posology and method of administration

If the feet are infected, they should be washed and dried thoroughly especially between the toes before applying the cream.

The cream should be applied thinly and evenly to the affected areas two or three times per day and rubbed in gently. A strip of cream (1/2cm long) is enough to treat an area of about the size of the hand.

The symptoms of skin infection, such as itching or soreness, should improve within a few days of treatment although signs such as redness and scaling may take longer to disappear. If symptoms persist, please consult your doctor. Patients should notify their physician if there is no improvement after 4 weeks of treatment.

It can be applied anytime of the day. Use as directed by doctor or pharmacist.

To ensure complete healing, the treatment should be continued according to the indications as specified below even if symptoms disappear:

- Athlete's foot, ringworm, fungal infection of the tissues adjacent to the nails, fungal infection of the skin folds: 3-4 weeks or as directed by physicians.
- Erythrasma (skin redness / irritation): 2-4 weeks or as directed by physicians.
- White spots: 1-3 weeks or as directed by physicians.

Route of Administration: For external and topical use only.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

The cream contains stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. It is preferable to avoid the use of clotrimazole during the first trimester of pregnancy.

Lactation

There are no data on the excretion of clotrimazole into human milk. However, systemic absorption is minimal after administration and is unlikely to lead to systemic effects. As a precautionary measure, breastfeeding should be discontinued during treatment with clotrimazole.

Fertility

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

4.7 Effects on ability to drive and use machines

Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible.

- **Immune system disorders:**
Anaphylactic reaction, angioedema, hypersensitivity.
- **Vascular disorders:**
Syncope, hypotension.
- **Respiratory, thoracic and mediastinal disorders:**
Dyspnoea.
- **Skin and subcutaneous tissue disorders:**
Blister, dermatitis contact, erythema, paraesthesia, skin exfoliation, pruritus, rash, urticaria, stinging skin / burning sensation skin.
- **General disorders and administration site conditions:**
Application site irritation, application site reaction, oedema, pain.

Some people may be allergic to the cream. If the patient is allergic, a reaction will occur soon after he / she starts using it. If he / she experiences an allergic reaction, he / she should stop using the cream.

Signs of an allergic reaction may include:

- Rash.
- Swallowing or breathing problems.
- Swelling of lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

- Discomfort / pain.

After applying the cream, the patient might experience:

- Itching, rash, blisters, burning, discomfort, swelling, irritation or peeling of skin.

Visit doctor or pharmacist immediately if there are any side effects after using this cream.

4.9 Overdose

No reports are available on cases of overdose. There is no specific antidote. Topical clotrimazole is intended for cutaneous use only. In the case of cutaneous overdose patients should be managed by symptomatic care; patients should wash off the product with water and cleanser, discontinue use and see their physician so appropriate therapy can be implemented as needed. In the case of ingestion of an overdose, patients should see their physician and be managed by symptomatic and supportive care.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives.

ATC Code: D01A C01.

Mechanism of Action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.

The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

6 PHARMACEUTICAL PARTICULARS

6.1 Shelf life

3 years.

6.2 Special precautions for storage

Store at temperature below 30°C.

Protect from light and moisture.

Keep out of reach of children.

Jauhkan daripada capaian kanak-kanak.

6.3 Nature and contents of container

The cream is filled into aluminium tubes. Pack sizes available are 20g, 20g x 40 and 20g x 50.

Not all pack sizes may be marketed.

7 MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)

Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,

43000 Kajang, Selangor, Malaysia.

Ordering Line: 1 800 88 3027

Product Info: 1 800 88 3679

8 DATE OF REVISION OF THE TEXT

29/05/2026