

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Daktarin Aktiv Spray Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Miconazole nitrate 0.16% w/w

(Each gram of spray contains 1.6 mg of miconazole nitrate)

Excipient with known effect: 1 g of powder contains 255 mg (10% w/w) ethanol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray powder

Spray leaving a white powdery residue

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cutaneous administration for the treatment and prevention of athlete's foot.

4.2 Posology and method of administration

Apply to infected area twice daily until the lesions are healed.

Method of Administration: Cutaneous use.

4.3 Contraindications

Hypersensitivity to the active substance, other imidazole derivatives or to any of the excipients listed in section 6.1

Not to be used on hair infections, nail infections or broken skin.

4.4 Special warnings and precautions for use

The spray should be kept away from the eyes and mucous membranes.

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Daktarin Aktiv Spray Powder and with other miconazole topical formulations (see Adverse Reactions). If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

Daktarin Aktiv Spray Powder contains talc. Avoid inhalation of the powder to prevent irritation of the airways. In particular, when treating infants and children, careful application should be used to prevent inhalation by the child. Daktarin Aktiv Spray Powder contains ethanol. This medicine contains 255 mg (10% w/w) ethanol in each gram powder. It may cause burning sensation on damaged skin.

Miconazole administered systemically is known to inhibit CYP3A4/2C9, which can lead to prolonged effects of warfarin or other vitamin K antagonists. While systemic absorption is limited with topical formulations, the concomitant use of Daktarin Aktiv Spray Powder and warfarin or other vitamin K antagonists should be done with caution and the anticoagulant effect should be carefully monitored and titrated. Patients should be advised of the symptoms of bleeding events and to immediately stop treatment with miconazole and seek medical advice should they occur (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on warfarin or other vitamin K antagonists, caution should be exercised and anticoagulant effect should be monitored.

4.6 Fertility, pregnancy and lactation

Pregnancy

In animals, miconazole nitrate has shown no teratogenic effects but is foetotoxic at high oral doses. Only small amounts of miconazole nitrate are

absorbed following topical administration. However, as with other imidazoles, miconazole nitrate should be used with caution during pregnancy.

Breast-feeding

Topically applied miconazole is minimally absorbed into the systemic circulation and it is not known whether miconazole is excreted in human breast milk. Caution should be exercised when using topically applied miconazole products during lactation.

4.7 Effects on ability to drive and use machines

Daktarin Aktiv Spray Powder has no influence on the ability to drive and use machines.

4.8. Undesirable effects

Adverse drug reactions from spontaneous reports during the worldwide postmarketing experience with Daktarin that meet threshold criteria are included. The adverse drug reactions are ranked by frequency, using the following convention:

Very common $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$, $< 1/1,000$

Very rare $< 1/10,000$, including isolated reports

The frequencies provided below reflect reporting rates for adverse drug reactions from spontaneous reports, and do not represent more precise estimates of incidence that might be obtained in clinical or epidemiological studies.

Immune system disorders

Very rare: anaphylactic reaction, hypersensitivity,

Skin and subcutaneous tissue disorders

Very rare: Angioedema, urticaria, contact dermatitis, rash, erythema, pruritus, skin burning sensation

General disorders and administration site conditions

Rare: application site reactions, including application site irritation

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any

suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Cutaneous use: Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy.

Treatment

Daktarin Aktiv Spray Powder is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered desirable.

Accidental inhalation of talc-containing powder: Massive accidental aspiration of Daktarin Aktiv Spray Powder may cause impaction blockage of airways. Respiratory arrest should be treated with intensive supportive therapy and oxygen. If respiration is compromised, endotracheal intubation, removal of impacted material, and assisted breathing should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: (Antifungals for dermatological/topical use; imidazole derivative) *ATC code*: D01A C02.

Miconazole nitrate is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It possesses a wide antifungal spectrum and has some antibacterial activity.

5.2 Pharmacokinetic properties

Absorption: There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically.

Distribution: Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%).

Metabolism and Excretion: The small amount of miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of local irritation, single and repeated dose toxicity, genotoxicity, and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearalkonium hectorite
Ethanol
Hydrocarbon propellant
Sorbitan sesquioleate
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep out of the sight and reach of children.
Caution Flammable
Pressurised container
Protect from light
Do not expose to temperatures exceeding 50°C

6.5 Nature and contents of container

Three piece tinplate aerosol container with epoxy-phenolic lining and welded side seam with protective polyester side strip.
1 inch opening to accommodate a standard aerosol valve.

The aerosol container contains 100g of product.

6.6 Special precautions for disposal and other handling

Shake well. Hold can 3 inches from skin, then generously spray affected area.

Pressurised container: Protect from sunlight and do not expose to temperatures exceeding 50°C.

Do not pierce or burn, even after use.

Do not spray on or near a naked flame or any incandescent material.

Keep away from sources of ignition - No smoking.

Do not spray near, or place on, polished or painted surfaces.

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

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0306

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/08/2008

10 DATE OF REVISION OF THE TEXT

12/03/2026

