DYNAREX ANTIFUNGAL POWDER- miconazole powder
Dynarex Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

1236 Dynarex Antifungal Powder NDC 67777-316-01

Active Ingredient

Active Ingredient	Purpose
Miconazol 2%	Antifungal

Purpose

Uses

For external treatment of fungal infections such as athlete's foot, jock itch, sweat rash, infected diaper rash and fungal infections affecting the skin folds e.g. armpits, groin, or under the breasts.

Warnings

For external use only.

Consult a doctor or pharmacist before using this product if you:

■ Are sensitive to the listed ingredients or any similar medications ■ Are pregnant, planning a pregnancy or breastfeeding

When using this product:

You may occasionally experience some side effects. These are rare and consist of local skin irritation or rashes, which occur if you are unusually sensitive to the ingredients listed.

Do Not Use

Do not use:

■ if you are sensitive to any of the active or inactive ingredients listed ■ if the infection is on your scalp or nails.

Cautions

Please read this label carefully before use.

• Dynarex Antifungal Powder is not suitable for the treatment of fungal infections of the scalp or nails, and you should talk to your doctor or pharmacist for alternative

treatments for these conditions. In order to ensure successful treatment, it is important to use the powder regularly and to continue for at least 10 days after the disappearance of symptoms. This prevents the infection from reoccurring.

• Remember that most fungal infections are very infectious and can easily be passed on to other family members. In order to prevent this happening, it is important to ensure that anyone who has an infection avoids sharing clothes, towels, or shoes with other family members. After applying the powder, wash and dry your hands thoroughly. If your skin condition does not improve after one week's use, please consult your doctor or pharmacist.

• If you forget to apply the powder, do not apply the missed dose, but apply the next dose as usual and continue as normal. Do not apply two doses at the same time.

Interactions

If you are taking oral anticoagulants (drugs used to thin the blood, such as Warfarin), talk to your doctor or pharmacist before use.

Overdose

Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy. In case of accidental ingestion of powder go to the hospital immediately.

Directions

Sprinkle onto the affected area twice daily. It can be safely applied to broken skin and may also be sprinkled onto clothes and footwear, which come into contact with the infected area.

Other information

Keep the medicine in the original packaging in a dry place, at a temperature not exceeding 30ºC/86ºF. Protect from light. Do not use after the expiry date shown on the pack.

Keep Out Of Reach Of Children

Keep Out Of Reach Of Children

Do not let the powder get into your eyes. This product contains talc. Do not breathe in the powder as this may cause irritation of the airways. This is especially important for children and infants. If swallowed, contact a poison control center immediately.

Inactive ingredients

Colloidal silicon dioxide, talc.

Principal Display panel

Dynarex Antifungal Powder 1236

AntiPowGP.jpg

DYNAREX ANTIFUNGAL POWDER

miconazole powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-316
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-316-02	24 in 1 CASE	05/19/2016	
1	NDC:67777-316-01	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/19/2016	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Revised: 11/2022 Dynarex Corporation