

CLOTRIMAZOLE CREAM 1%- clotrimazole cream 1% cream

SOLA Pharmaceuticals

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.

Clotrimazole Cream 1% - Antifungal Cream

Active Ingredient

Clotrimazole 1%

Purpose

Antifungal

Usage

- For External treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis).
- Relieves itching, cracking scaling irritation and chafing associated with these conditions.

Warnings

Do not use on children under 2 years of age unless directed by a doctor.

For external use only.

Avoid contact with eyes.

If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch), discontinue use and consult a doctor.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.

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Directions

- Clean the affected area and dry thoroughly. Apply a layer of cream over the affected area twice daily morning and night or as directed by doctor.
- Supervise children in the use of this product.
- For athlete's foot pay special attention to the spaces between toes. Wear well fitting ventilated shoes and change shoes and socks at least once daily.
- For athlete's foot and ringworm use daily for 4 weeks.
- For jock itch use daily for 2 weeks.

- If condition persist longer consult a doctor.
- This product is not effective on scalp or nails.

Inactive Ingredients

Cetomacragol 1000, Cetostearyl alcohol, Liquid paraffin, Methyl Paraben, Propyl paraben, Propylene glycol, Purified water, White soft paraffin.

Other Information

- Store between 20°C and 25°C (68°F and 77°F)

Questions or comments?

Call 1-866-747-7365

Package Display Panel

Questions or comments?

Call 1-866-747-7365

Manufactured for : SOLA Pharmaceuticals

Baton Rouge, LA 70810

Store in a dry, cool place

For Comments or Questions, call 866-747-7365

Clotrimazole 1% Cream

NDC 70512-100-30

Qty: 28.4g

NDC 70512 -0100-30

Anti-fungal

Clotrimazole

CREAM USP, 1%

Compare to the active ingredient of Lotrimin®*



CURES MOST ATHLETE'S FOOT

Relieves Itching & Burning
Greaseless & Non Staining

Clotrimazole

CREAM USP, 1%



Clotrimazole

CREAM USP, 1%

Anti-fungal

NET WT. 1 OZ. (28.4 G)

Clotrimazole

CREAM USP, 1%

*This product is not manufactured or distributed by MSD Consumer Care, Inc., Owner of the registered trademark Lotrimin AF®.



Manufactured for:
SOLA PHARMACEUTICALS
Baton Rouge, LA 70810

Drug Facts (Continued)
Active Ingredients: Clotrimazole 1000, Cetostearyl alcohol, Liquid paraffin, Methyl Paraben, Propyl Paraben, Propylene Glycol, Purified water, White soft paraffin.
Questions or comments? Call 1-866-747-7365.

| | |
|---|---|
| Drug Facts | |
| Active Ingredient Clotrimazole, USP 1% Purpose Antifungal | Uses: For external treatment of most athlete's foot (tinea pedis) jock itch (tinea cruris), Ringworm (tinea corporis). Relieves itching, cracking, scaling irritation and chafing associated with these conditions. |
| Warnings Do not use on children under 2 years of age unless directed by a doctor. For external use only. Avoid contact with eyes. If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch), discontinue use and consult a doctor. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away. | Directions: Clean the affected area and dry thoroughly. Apply a layer of cream over the affected area twice daily morning and night or as directed by doctor. Supervise children in the use of this product. For athlete's foot pay special attention to spaces between toes. Wear well fitting ventilated shoes and change shoes and socks at least once daily. For athlete's foot and ringworm use daily for 4 weeks. For jock itch use daily for 2 weeks. If condition persists longer consult a doctor. This product is not effective on scalp and nails. |
| Other Information Store between 20°C and 25°C (68°F and 77°F). This product is not effective on scalp and nails. | Drug Facts (Continued) |

Cures Most Athlete's Foot

CREAM USP, 1%

Clotrimazole



Relieves Itching
& Burning

NDC 70512 -0100-30

Anti-fungal

Clotrimazole

CREAM USP, 1%

Compare to the active ingredient of Lotrimin®*

TREATS ATHLETE'S FOOT, JOCK ITCH, & RINGWORM

Relieves Itching & Burning
Greaseless & Non Staining

Clotrimazole

CREAM USP, 1%



Clotrimazole

CREAM USP, 1%

Anti-fungal

NET WT. 1 OZ. (28.4 G)

Clotrimazole

CREAM USP, 1%

7 05120 10030 1

Manufactured for:
SOLA PHARMACEUTICALS
Baton Rouge, LA 70810

Drug Facts (Continued)

Active ingredient: Clotrimazole, USP 1%
Purpose: Antifungal

Directions:
Clean the affected area twice daily morning and night or as directed over the affected area and dry thoroughly. Apply a layer of cream.

Warnings:
■ For external treatment of most athlete's foot (tinea pedis) jock itch (tinea cruris), Ringworm (tinea corporis),
■ Relieves itching, cracking scaling irritation and chafing associated with these conditions.

Do not use on children under 7 years of age unless directed by a doctor.

For external use only

Avoid contact with eyes.

■ If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch), discontinue use and consult a doctor.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.

Other information ■ Store between 20°C and 25°C (68°F and 77°F)

■ This product is not effective on scalp and nails.

■ If condition persists longer consult a doctor.

■ For jock itch use daily for 2 weeks.

■ For athlete's foot and ringworm use daily for 4 weeks.

■ For athlete's foot use daily.

■ Wear well fitting ventilated shoes and change shoes and socks at least once daily.

■ Supervise children in the use of this product.

■ For athlete's foot pay special attention to spaces between toes.

*This product is not manufactured or distributed by MSD Consumer Care, Inc., Owner of the registered trademark Lotrimin A.F.®.

CREAM USP, 1%

Clotrimazole



Relieves Itching
& Burning



NDC 70512-0100-30

TREATS ATHLETE'S FOOT,
JOCK ITCH, & RINGWORM

Clotrimazole

CREAM USP, 1%

Anti-fungal

NET WT. 1 OZ. (28.4 G)

8X3mm

Drug Facts

Active ingredient

Clotrimazole, USP 1%

Purpose

Antifungal

Uses: ■ For external treatment of most athlete's foot (tinea pedis) jock itch (tinea cruris), Ringworm (tinea corporis). ■ Relieves itching, cracking scaling irritation and chafing associated with these conditions. **Warnings** ■ Do not use on children under 2 years of age unless directed by a doctor.

■ For external use only ■ Avoid contact with eyes. ■ If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch), discontinue use and consult a doctor. ■ Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away. **Directions:** ■ Clean the affected area and dry thoroughly. Apply a layer of cream over the affected area twice daily morning and night or as directed by doctor. ■ Supervise children in the use of this product. ■ For athlete's foot pay special attention to spaces between toes. Wear well fitting ventilated shoes and change shoes and socks at least once daily. ■ For athlete's foot and ringworm use daily for 4 weeks. ■ For jock itch use daily for 2 weeks. ■ If condition persists longer consult a doctor. ■ This product is not effective on scalp and nails. **Other information** ■ store between 20°C and 25°C (68°F and 77°F) **Inactive ingredients:** Cetamacragol 1000, Cetostearyl alcohol, Liquid paraffin, Methyl Paraben, Propyl Paraben, Propylene Glycol, Purified water, White soft paraffin.

Questions or comments? Call 1-866-747-7365.

Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70810

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1mm

MSD

NDC 70512-100-15

QTY 14.2

NDC 70512 -0100-15

Anti-fungal

Clotrimazole

CREAM USP, 1%

Compare to the active ingredient of Lotrimin[®]*

TREATS ATHLETE'S FOOT, JOCK ITCH, & RINGWORM

Relieves Itching & Burning
Greaseless & Non Staining

Clotrimazole

CREAM USP, 1%



Clotrimazole

CREAM USP, 1%

Anti-fungal

NET WT. 0.5 OZ. (14.2 G)

Clotrimazole

CREAM USP, 1%

Drug Facts (Continued)

Inactive ingredients: Cetomacrogol 1000, Cetostearyl alcohol, Liquid paraffin, Methyl Paraben, Propyl Paraben, Propylene Glycol, Purified water, White soft paraffin.

Questions or comments? Call 1-866-747-7365.

Drug Facts

Active ingredient
Clotrimazole, USP 1%..... Antifungal

Purpose
Antifungal

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Drug Facts (Continued)

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Other information ■ store between 20°C and 25°C (68°F and 77°F)

Manufactured for:
SOLA PHARMACEUTICAL
Baton Rouge, LA 70810

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Relieves Itching
& Burning

Clotrimazole

CREAM USP, 1%



CLOTRIMAZOLE CREAM 1%

clotrimazole cream 1% cream

Product Information

| | | | |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70512-100 |
|--------------|----------------|--------------------|---------------|

| | | | | |
|--|--|---|----------------------|--------------------|
| Route of Administration | | TOPICAL | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65) | | CLOTRIMAZOLE | 10 mg in 1 g | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| MINERAL OIL (UNII: T5L8T28FGP) | | | | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| CETETH-20 (UNII: I835H2IHHX) | | | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:70512-100-30 | 1 in 1 CARTON | 04/14/2020 | |
| 1 | | 30 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:70512-100-15 | 1 in 1 CARTON | 10/21/2021 | |
| 2 | | 14.2 g in 1 TUBE; 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 | | 04/14/2020 | |

Labeler - SOLA Pharmaceuticals (080121345)