ASTONEA ANTIFUNGAL CREAM TOLNAFLATE- tolnaftate cream
ASTONEA LABS PRIVATE LIMITED

ASTONEA Antifungal Cream TOLNAFLATE

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot with daily use
- for effective relief of itching, burning and cracking

Warnings

For external use only

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

When using this product avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

adults and children 2 years of age and over:

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily
- to prevent athlete's foot, apply once or twice daily (morning and/or night)
- this product is not effective on the scalp or nails

Children under 2 years of age: consult a physician

Other information

store between 20° to 25°C (68° to 77°F)

- do not use if tube seal under cap is broken

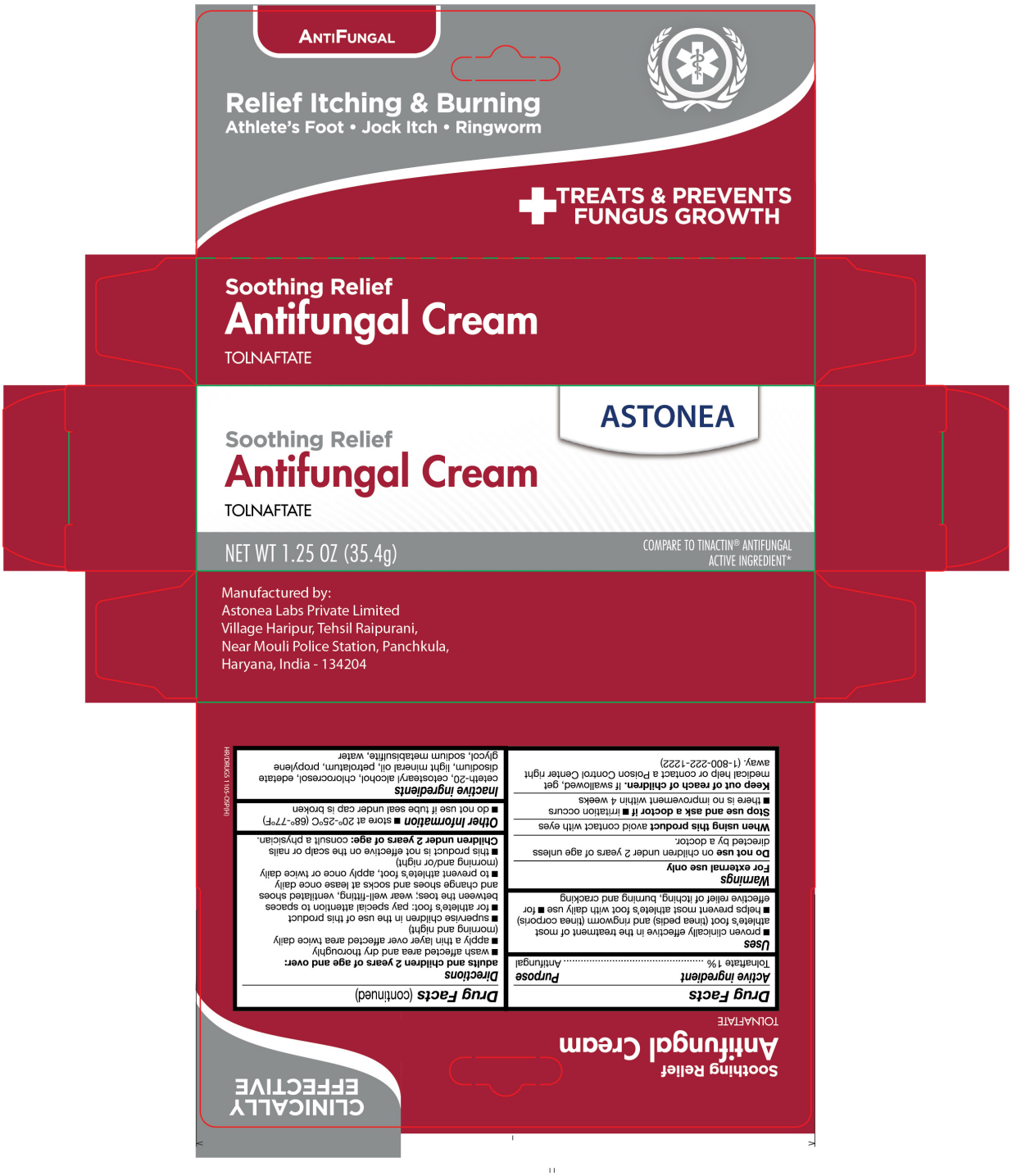
Inactive ingredients

ceteth-20, cetostearyl alcohol, chlorocresol, edetate disodium, light mineral oil, petrolatum, propylene glycol, sodium metabisulfite, water

Questions?

Toll Free 1-866-326-1313

PRINCIPAL DISPLAY PANEL - 35.4 g Tube Carton



ASTONEA ANTIFUNGAL CREAM TOLNAFLATE

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77338-934
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W53O7109)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE (UNII: BWZ7K44R51)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-934-01	1 in 1 CARTON	03/05/2024	
1		35.4 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 Drug	M005	03/05/2024	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 3/2024 ASTONEA LABS PRIVATE LIMITED