

CLOTRIMAZOLE- clotrimazole cream
Rebel Distributors Corp.

Clotrimazole Drug Facts

Active ingredient

Clotrimazole 50mg

Purpose

Vaginal antifungal/external vulvar antifungal

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away.

Uses

Treats vaginal yeast (candida) infections

Relieves external vulvar itching and irritation associated with a yeast infection

Warnings

For vaginal or external vulvar use only.

Do not use:

◦ If you have abdominal pain, fever, or a foul smelling vaginal discharge.

Contact your doctor immediately.

◦ In children less than 12 years of age.

Ask a doctor before use if you have:

◦ vaginal or vulvar itching and discomfort for the first time. If you have had a doctor diagnose a vaginal yeast infection before and have the same symptoms now, use this cream as directed for 7 days in a row.

◦ symptoms that return within 2 months or infections that do not clear up easily with proper treatment. You could be pregnant, or there could be a serious underlying medical cause for your infections, including diabetes or a damaged immune system (including damage from infection from HIV - the virus that causes AIDS). Please read enclosed educational pamphlet.

When using this product do not use tampons.

Stop use and ask a doctor if:

symptoms do not get better in 3 days or infection isn't gone in 7 days. You may have a condition other than a yeast infection.

If pregnant or breast-feeding, ask a health professional before use.

Directions

◦ before using this product, read the enclosed pamphlet

◦ fill the applicator and insert one applicatorful of cream into the vagina, preferably at bedtime. Repeat

this procedure 7 days in a row. Throw applicator away after use.

° for relief of external vulvar itching, squeeze a small amount of cream onto your finger and gently spread the cream onto the irritated area of the vulva. Use once or twice a day for up to 7 days as needed to relieve external vulvar itching. The cream should not be used for vulvar itching due to causes other than a yeast infection.

Other Information

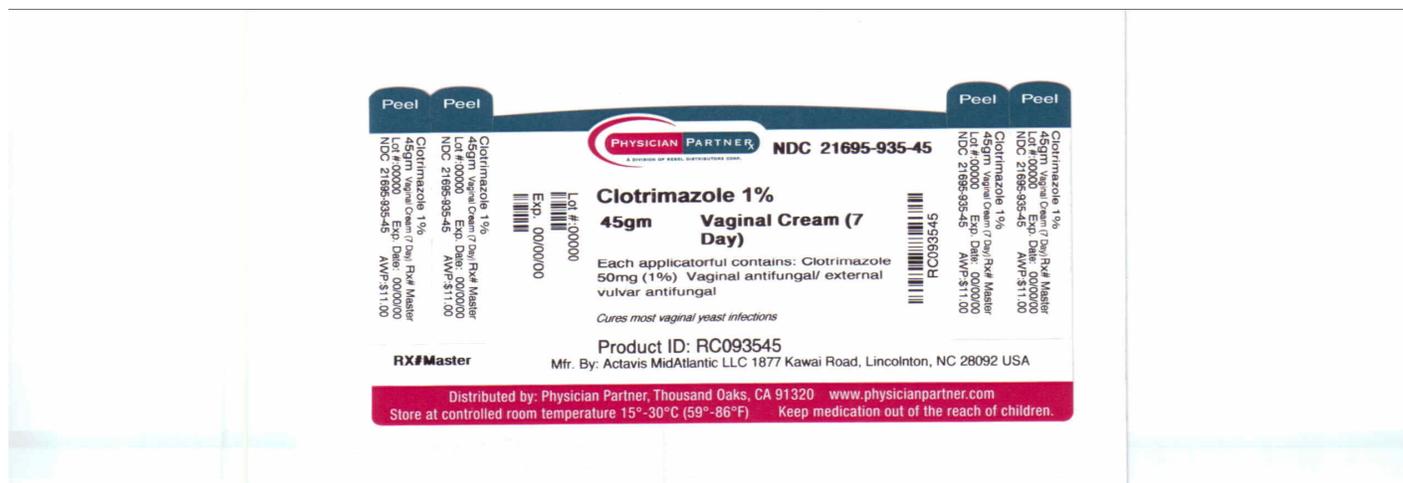
- ° store at room temperature between 2° and 30°C (36° to 86°F)°
- ° see end flaps of carton and tube for lot number and expiration date
- ° **safety sealed:** the tube opening should be sealed. If seal has been punctured or is not visible, do not use the product.

Questions? 1-800-432-8534 (select option #2) between 9 am and 4 pm EST, Monday-Friday.

Inactive ingredients

benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sodium phosphate monobasic, sorbitan monostearate.

Package/Label Principal Display Panel



CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-935(NDC:0472-0220)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OCTYLDODECYL STEARATE (UNII: K6F16QGO28)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0K00R)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-935-45	45 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074165	07/16/1993	

Labeler - Rebel Distributors Corp. (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp.		118802834	RELABEL, REPACK

Revised: 5/2011

Rebel Distributors Corp.