

CANESTEN V- clotrimazol cream
GENESIS IMPORTS & EXPORTS LLC

ACTIVE INGREDIENTS

CLOTRIMAZOLE 2%

PURPOSE

Vaginal Antifungal

USE

- TREATS VAGINAL YEAST INFECTIONS
- RELIEVES EXTERNAL ITCHING AND IRRITATION DUE TO A VAGINAL YEAST INFECTION

WARNINGS

FOR VAGINAL USE ONLY

DPO NOT USE IF YOU HAVE NEVER HAD VAGINAL YEAST INFECTION DIAGNOSED BY

A DOCTOR

Ask A Doctor before if you have

- **Vaginal itching and discomfort for the first time**
- **lower abdominal, back or shoulder pain, fever, chillis, nausea, vomiyng, or foul-s melling vaginal discharge. You may have a more serious condition.**
- **Vaginal yeast infections often (such as once a mont h or 3 in 6 month). You can be pregnat or have a serious underlying medical cause for your sy mptoms, including, inclyding diabetes or a weakened immune system.**
- **been exposed to the human immunodeficiency virus (HIV) that causes AIDS**

STOP USE A ND ASK A DOCTOR IF

- **SYMPTOMS DO NOT GE T BETTER IN 3 DAYS**
- **SYMPTOMS LAST MORE THAN 7 DAYS**
- **DO YOU GET A RUSH OR HIVE, ABDOMINAL PAIN, FEVER , CHILLS, NAUSEA, VOMITING, OR A FOU L-SMELLING VAGINA L DISCHARGE .**

IF PREGNANT OR BREAST-FEEDING, ASK A HEALTH PROFESSIONAL BEFORE USE

KEEP OUT OF CHILDREN, IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT A WAY

DIRECTION

- **BEFORE US EINF THIS PRODUCT READ THE ENCLOSED EDUCATIONAL BROCHURE FOR COMPLETE DIRECTIONS AND INFORMATION**
 - **ADULTS AND CHILDREN 12 YEARS OF AGE AND OVER:**

1. **VAGINA CREAM:INSERT ONE APPLICATOTFUL OF CREAM INTO TEH VAGINA AT BEDTIME FOR 3 DAYS IN A ROW. TROW APPLICATOR AWAY AFTER USE.**
2. **EXTERNAL USE: CREAM :USE THE SAME TUBE OF CREAM IF YOU HAVE ICHING AND IRRITATION ON THE SKIN OUTSIDE THE VAGINA. SQUEEZE SMALL AMOUNT OF CREAM ONTO YOUR FINGERTIP. APPLY TO ICHY, IRRITATED SKIN OUTSIDE THE VAGINA.. USE 2 TIMES DAULY FOR UP TP 7 DAY AS NEEDED**
3. **CHILDREN UNDER 12 YEARS OF AGE : ASK A DOCTOR**

OTHER INFORMATION

- TO OPEN: UNSCREW CAP, USE POINTED END ON CAP TO PUNCTURE SEAL

DO NOT USE IF CARTON IS OPENED

- SAFETY SEALED: THE TUBE OPENING SHOULD BE SEALED. IF THE SEAL HAS BEEN PUNCTURED OR IS NOT BISIBLE, DO NOY USE THE PRODUCT
- STORE BETWEEN 20 TO 25 C (68 TO 77 F)
- SEE FLAP OF CARTON OR CRIMP OF TUBE DOR LOT NUMBER AND EXPIRATION DATE

Banzyl alcohol

Cetostearyl alcohol

cetyl esters wax

octydocanol

polysorbate 60

water

sorbitan monostearate



CANESTEN V

clotrimazol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-200
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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POLYSORBATE 60 (UNII: CAL22UVI4M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
WATER (UNII: 059QF0K00R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69772-200-01	1 in 1 CARTON	05/17/2016	
1		21 g in 1 TUBE, WITH APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021143	05/17/2016	

Labeler - GENESIS IMPORTS & EXPORTS LLC (078760958)

Registrant - TERESA CECENA (078760958)

Establishment

Name	Address	ID/FEI	Business Operations
GENESIS IMPORTS & EXPORTS LLC		078760958	relabel(69772-200)

Establishment

Name	Address	ID/FEI	Business Operations
G.P. Grenzach produktions gmbh		332090930	sterilize(69772-200)

Establishment

Name	Address	ID/FEI	Business Operations
Grenzach Produktions GmbH		342326972	api manufacture(69772-200)

Establishment

Name	Address	ID/FEI	Business Operations
BAYER DE MEXICO SA DE CV		588165709	manufacture(69772-200)