SCHEDULING STATUS S2

PROPRIETARY NAME (AND DOSAGE FORM)
VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM

COMPOSITION
VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM contains econazole nitrate 10,0 mg per gram.

Preservative: benzyl alcohol 1 % *m/m*

PHARMACOLOGICAL CLASSIFICATION
A.18.6 Vaginal Preparations

PHARMACOLOGICAL ACTION
Econazole nitrate is an antimycotic agent.

INDICATIONS
For the relief of vaginal itching, burning and discharge associated with recurrent vaginal yeast infections (vaginal candidiasis).

CONTRAINDICATIONS
Hypersensitivity to econazole nitrate and any other compound in the formulation.

WARNINGS
VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM should only be used if a vaginal yeast infection has been diagnosed previously by medical practitioner and you have the same symptoms now, otherwise consult your doctor. These symptoms include itching and burning of the vagina and sometimes a white discharge.

If there is no improvement in 3 days or if symptoms have not disappeared within 7 days, a medical practitioner should be consulted as not all vaginal infections are caused by yeasts.

A medical practitioner should be consulted in case of abdominal pain, fever or a foul-smelling vaginal discharge before or during use of this medication. If symptoms recur within 2 months, consult a medical practitioner.

VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM should not be used during pregnancy or breastfeeding except on the advice of a medical practitioner.

Do not use in girls under 12 years of age, except on the advice of a medical practitioner. If skin rash or new irritation occurs, discontinue use.

DOSAGE AND DIRECTIONS FOR USE
Unless otherwise prescribed by a medical practitioner, daily introduce one applicator charge of VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM deeply into the vagina, preferably while assuming a supine position just before retiring at night, for a period of 2 weeks. The treatment must be continued even during menstruation and even after the disappearance of subjective complaints (itching, discharge).

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Local irritation may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Accidental ingestion can lead to nausea and vomiting which should be treated symptomatically. For further information, see "SIDE EFFECTS AND SPECIAL PRECAUTIONS". Treatment should be symptomatic and supportive.

IDENTIFICATION
White homogeneous cream with no contaminants.

PRESENTATION
VARI-ECONAZOLE NITRATE 1 % *mm* VAGINAL CREAM is packed into aluminium lacquered tubes with a white piercing cap containing 80 g with applicator.

STORAGE INSTRUCTIONS
Store at or below 25 °C. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
36/18.6/0130

NAME AND BUSINESS ADDRESS OF THE APPLICANT
LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6
10 Church Street
Durbanville 7551

DATE OF PUBLICATION OF THIS PACKAGE INSERT.
Date of registration: 6 June 2003
Date of revision: 1 July 2021

APPROVED
2021/07/13

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SKEDULERINGSTATUS S2

EIENDOMSNAAM
VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM

SAMESTELLING
VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM bevat ekonasoolnitraat 10,0 mg per gram.
Preserveermiddel: bensielalkohol 1 % *m/m*.

FARMAKOLOGIESE KLASSIFIKASIE
A. 18.6 Vaginale preparate

FARMAKOLOGIESE WERKING
Ekonasoolnitraat is 'n anti-mikotiese middel.

INDIKASIES
Vir die verligting van vaginale jeuk, brandgevoel en afskeiding vanweë terugkerende vaginale gisinfeksies (vaginale kandidiase).

KONTRA-INDIKASIES
Hipersensitiwiteit teenoor ekonasoolnitraat of enige ander verbinding in die formulering.

WAARSKUWINGS
VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM moet slegs gebruik word as 'n vaginale gisinfeksie voorheen deur 'n mediese praktisyn gediagnoseer is en u nou dieselfde simptome ervaar. Andersins moet u u dokter raadpleeg. Hierdie simptome is onder meer 'n gejeuk en brandgevoel van die vagina en soms 'n wit afskeiding.

As daar na 3 dae geen verbetering is nie of as die simptome nie binne 7 dae verdwyn nie, moet 'n mediese praktisyn geraadpleeg word omdat nie alle vaginale infeksies deur giste veroorsaak word nie.

'n Mediese praktisyn moet geraadpleeg word in geval van buikpyn, koors of 'n vaginale afskeiding met 'n slegte reuk voor of tydens gebruik van hierdie medikasie. As die simptome binne 2 maande terugkeer, moet 'n mediese praktisyn geraadpleeg word.

VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM moet nie tydens swangerskap of borsvoeding gebruik word nie, behalwe op advies van 'n mediese praktisyn.

Die produk moet nie in dogters jonger as 12 jaar gebruik word nie, behalwe op advies van 'n mediese praktisyn. Staak gebruik as 'n veluitslag of nuwe irritasie voorkom.

DOSIS EN GEBRUIKSAANWYSINGS
Tensy andersins deur 'n mediese praktisyn voorgeskryf, plaas oor 'n periode van 2 weke daagliks een aanwender vol VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM diep in die vagina, verkieslik in 'n liggende posisie en net voordat u gaan slaap. Die behandeling moet selfs tydens menstruasie en selfs nadat die simptome (jeuk, afskeiding) verdwyn het, volgehou word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREëLS
Lokale irritasie kan voorkom.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Onopsetlike inname kan tot naarheid en braking lei wat simptomaties behandel moet word. Vir verdere inligting kyk NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREëLS. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Wit homogene room met geen kontaminante nie.

AANBIEDING
VARI-ECONAZOLE NITRATE 1 % *m/m* VAGINAL CREAM word verpak in lakbedekte aluminiumbuise wat 80 g bevat met 'n wit deursteekdoppie en 'n aanwender.

BEWARINGSINSTRUKSIES
Beg by of onder 25 °C. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
36/18.6/0130

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT
LeBasi Pharmaceuticals (Edms) Bpk.
San Domenico-gebou, Eenheid 6
Kerkstraat 10
Durbanville 7551

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
Datum van registrasie: 6 Junie 2003
Datum van hersiening: 1 Julie 2021

APPROVED
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SKEDULERINGSTATUS S2

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Satisfactory

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