PACKAGE INSERT

SCHEDULING STATUS: S1

PROPRIETARY NAME (AND DOSAGE FORM):

GYNEZOL (VAGINAL CREAM)

COMPOSITION:
Each 1 g of cream contains:

Clotrimazole	10 mg	
Preservatives:		
Nipastat	0,275	% m/m
Biopure 100	0,3	% m/m

PHARMACOLOGICAL CLASSIFICATION:
A .20.2.2 Fungicides.

PHARMACOLOGICAL ACTION:
Gynezol is a broad spectrum antimycotic with fungicidal properties.

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

CONTRA-INDICATIONS:
Possible hypersensitivity to clotrimazole.
The possibility of absorption of clotrimazole when administered vaginally cannot be excluded. Safety in pregnancy has not been established.

WARNINGS:
i) Use only if you have already had a vaginal yeast infection diagnosed by a medical practioner 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.
ii) If there is no improvement in 3 days or if symptoms have not disappeared within seven days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.
iii) Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during use of this medication.
iv) If symptoms recur within 2 months, consult a medical practitioner.
v) If you are pregnant or think you may be pregnant or are nursing, do not use this medication except on the advice of a medical practitioner.
vi) Do not use in girls under 12 years of age, except on the advice of a medical practitioner.
vii) If skin rash or new irritation occurs, discontinue use.

DOSAGE AND DIRECTIONS FOR USE:
Not intended for oral administration.
Fill enclosed vaginal applicator to the top (i.e. 5 g **Gynezol** vaginal cream). Insert deeply into the vagina every night on retiring for six consectutive days. This is best achieved when lying on the back with the legs pulled in a little towards the body. If individual cases should require it, two applications of 5 g vaginal cream can be used daily, i.e. one in the morning and one in the evening, for 6-12 days. The treatment should be continued even during menstruation and even if symptoms disappear.
For prevention of re-infection the partner should be treated locally with **Gynezol** cream at the same time. This preparation does not stain the underwear.

DIRECTIONS FOR USING THE APPLICATOR:
PREPARATION OF THE APPLICATOR:
1. Wash your hands thoroughly.
2. Screw the open end of one of the applicators over the opening of the tube of cream. The plunger of the applicator should be pushed right in at this stage.
3. Gently squeeze the bottom of the tube so that the cream fills the applicator to the top, pushing the plunger out to almost its full extent.
4. Unscrew the tube of cream and replace its cap.

INSERTING THE APPLICATOR:
5. Carefully insert the end of the applicator as deeply as possible into the vagina (making sure plunger does not fall out). This is best achieved when lying on the back with the legs pulled in a little towards the body.
6. Slowly push the plunger with the forefinger until it stops.
7. Remove the applicator from the vagina and discard it.

The surplus cream may be used to treat any inflammation of the vulva (outer vaginal area) and nearby areas. The cream chould be applied thinly and rubbed in gently 2-3 times a day. Follow your doctor's instructions.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Local reactions including irritation and burning may occur. Contact allergic dermatitis have been reported. **Gynezol** vaginal cream should only be administred to pregnant women under medical supervision, especially during the early stages of pregnancy.
In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See "Side-Effects and Special Precautions". In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

IDENTIFICATION:
A soft, white cream.

PRESENTATION
Tube of 50 g with 6 vaginal applicators packed into a unit carton.

STORAGE INSTRUCTIONS:
Store below 25 °C, in a dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
28/20.2.2/0418

NAME AND BUSINESS ADDRESS OF APPLICANT:
Gulf Drug Company (PTY) LTD.
22 Burnside Drive
Old Mill Industrial Park
Mount Edgecombe
4300

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