Approved Professional Information for Medicines for Human Use:

ASCENDOSPOR VAGINAL

SCHEDULING STATUS

S1

PROPRIETARY NAME (and dosage form):

ASCENDOSPOR VAGINAL (Cream)

COMPOSITION

Each 1 g of cream contains: Clotrimazole ……10 mg

Preservatives:

Nipastat …….. 0,275 % m/m

Imidurea ……. 0,300 % m/m

PHARMACOLOGICAL CLASSIFICATION

A.20.2.2 Fungicides

PHARMACOLOGICAL ACTION:

ASCENDOSPOR VAGINAL 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).

CONTRAINDICATIONS:

Possible sensitivity to clotrimazole. The possibility of absorption of clotrimazole when administered vaginally cannot be excluded. Safe use in pregnancy has not been established.

WARNINGS AND SPECIAL PRECAUTIONS:

Use only if you have already had a vaginal yeast infection diagnosed by a 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 three days or if symptoms have not disappeared within seven days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.

Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during use of this medication.

If symptoms recur within two months, consult a medical practitioner.

If you are pregnant or think you may be pregnant or are nursing, do not use this medication except on the advice of a medial practitioner.

Do not use in girls under twelve years of age, except on the advice of a medical practitioner.

If skin rash or new irritation occurs, discontinue use.

PREGNANCY AND LACTATION

Safety and efficacy in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

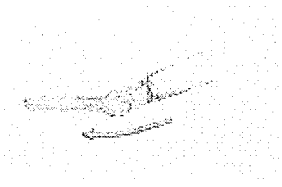
Fill enclosed vaginal applicator to the top (i.e. 5 g **ASCENDOSPOR VAGINAL** cream). Insert deeply into the vagina every night on retiring for six (or seven) **consecutive** nights, even during menstruation and even if symptoms should disappear. Apply the cream as per the directions under **"Directions for using the "GENTLE COMFORT" applicator".** If individual cases should require it, two applications of 5 g **ASCENDOSPOR VAGINAL** cream can be used daily, i.e. one in the morning and one in the evening, for six to twelve days.

For candida vulvitis or vulvo-vaginitis the vaginal cream should be applied thinly to the external genitalia two or three times a day for one to two weeks.

For the prevention of re-infection the partner should be treated locally with **ASCENDOSPOR VAGINAL** cream at the same time. **ASCENDOSPOR VAGINAL** cream preparations are colourless and do not stain the underwear.

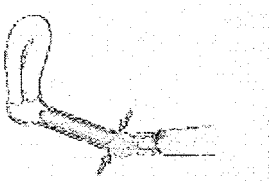
DIRECTIONS FOR USING THE "GENTLE COMFORT" APPLICATOR:

1. Puncture the nozzle of the tube of cream, using the cap.
2. Remove the nose cap from the point of the applicator.
3. Screw the applicator firmly on to the tube of the cream.
4. Holding the tube vertically, squeeze the cream into the applicator until it is filled to its tip.



5. Squeeze a little cream onto your fingertip to lubricate the point of the applicator.

6. Sitting on the edge of a toilet seat, or chair, hold the tube in a comfortable horizontal position before the vaginal opening in one hand, with the point of the applicator facing the vagina. Grasp the base of the shaft of the applicator between the forefinger and thumb of your free hand and gently guide the applicator shaft into the vagina, until the thumb touches your body.



7. Compress the applicator bulb between the thumb and first two fingers of the free hand to empty the bulb of cream.

8. Withdraw the applicator shaft from the vagina and clean it using soap and warm water or a tissue.

9. Replace the nose cap of the applicator and store the tube of cream with the applicator attached – thus keeping the cream sterile.

10. To apply the next dose of cream: Remove the nose cap and repeat steps 4 to 9.

11. Discard applicator after treatment course.

SIDE EFFECTS

Local reactions including irritation and burning may occur. Contact allergic dermatitis has been reported. In case of systemic absorption, lower abdominal cramps, increase in urine frequency or skin rashes may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See 'SIDE EFFECTS.

In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatments is symptomatic and supportive.

IDENTIFICATION:

Soft white cream.

PRESENTATION:

Tube of 50 g with 6 (six) individually wrapped vaginal applicators.

STORAGE INSTRUCTIONS:

Store at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

29/20.2.2/0199

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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