Approved Patient Information Leaflet for Medicines for Human Use:

ASCENDOSPOR VAGINAL

SCHEDULING STATUS: S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ASCENDOSPOR VAGINAL (Cream)

Each 1 g of **ASCENDOSPOR VAGINAL** Cream contains 10 mg clotrimazole.

Read all of this leaflet carefully before you start using ASCENDOSPOR VAGINAL.

ASCENDOSPOR VAGINAL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use ASCENDOSPOR VAGINAL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ASCENDOSPOR VAGINAL with any other person.
- Ask your pharmacist if you need more information or advice.

1. WHAT ASCENDOSPOR VAGINAL CONTAINS:

The active substance is clotrimazole

Each 1 g of **ASCENDOSPOR** VAGINAL cream contains 10 mg clotrimazole.

The preservatives are:

Nipastat …….. 0,275 % m/m

Imidurea …….. 0,300 % m/m

2. WHAT ASCENDOSPOR VAGINAL IS USED FOR:

ASCENDOSPOR VAGINAL cream is an antifungal cream used for the relief of vaginal itching, burning and discharge associated with recurrent vaginal yeast infections (vaginal candidiasis).

3. BEFORE YOU USE ASCENDOSPOR VAGINAL:

Do not use ASCENDOSPOR VAGINAL:

- If you are sensitive (allergic) to clotrimazole or any of the other ingredients (see **WHAT ASCENDOSPOR VAGINAL CONTAINS** section).
- If you are pregnant unless prescribed by a doctor.

WARNINGS

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 while 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 medical 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 Breast-feeding:

The safety of using **ASCENDOSPOR VAGINAL** in pregnancy and lactation has not been established.

Using other medicines with ASCENDOSPOR VAGINAL:

Always tell your healthcare professional if you taking any other medicine. This includes complementary or traditional medicines.

4.HOW TO USE ASCENDOSPOR VAGINAL:

Do not put the cream in your mouth or swallow it.

Do not share medicines prescribed for you with any other person.

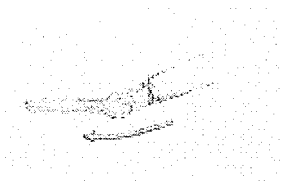
Always use **ASCENDOSPOR VAGINAL** cream exactly as your doctor or pharmacist has instructed you. You should check with your doctor of pharmacist if you are unsure.

- Fill enclosed vaginal applicator to the top (i.e. 5 g **ASCENDOSPOR VAGINAL** cream). Insert deeply into vaginal every night on retiring for six (or seven) **consecutive** nights, even during menstruation and even if symptoms should disappear. Apply the creams 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 inflammation of the vulva (vulvitis) or inflammation of the vulva and the vagina (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.

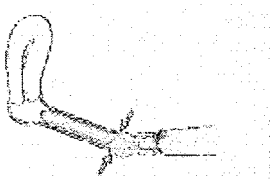
DIRECTIONS FOR USING THE "GENTLE COMFORT" APPLICATOR:

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.

Your doctor or pharmacist will tell you how long your treatment with **ASCENDOSPOR VAGINAL cream** will last. Do not stop the treatment earlier because you start feeling better. First check with your doctor.

If you have the impression that the effect of **ASCENDOSPOR VAGINAL** is too strong or too weak, tell your doctor or pharmacist.

If you use more ASCENDOSPOR VAGINAL than you should:

In case of accidental ingestion, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forgot to use ASCENDOSPOR VAGINAL:

Apply the cream as soon as possible and then continue the rest of your treatment as usual.

Effect when treatment with ASCENDOSPOR VAGINAL is stopped:

If you stop treatment before the prescribed time, the area will continue to itch. Therefore always use **ASCENDOSPOR VAGINAL** cream as prescribed.

4. POSSIBLE SIDE EFFECTS:

ASCENDOSPOR VAGINAL can have side effects.

Not all side effects reported for **ASCENDOSPOR VAGINAL** cream are included In this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects may occur:

- local reaction including irritation and burning.
- Localized rash or irritation of the skin (contact allergic dermatitis) has been reported. If this occurs, treatment should be discontinued.
- Lower abdominal cramps.
- Increase in urine frequency or skin rashes may occur, in the case of systemic absorption.

5. STORING AND DISPOSING OF ASCENDOSPOR VAGINAL:

- Store all medicines out of reach of children. Store at or below 25 ºC.
- Do not store in a bathroom.
- Do not refrigerate.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicine in drains or sewage systems (e.g. toilets).

6. PRESENTATION OF ASCENDOSPOR VAGINAL:

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

7. IDENTIFICATION OF ASCENDOSPOR VAGINAL:

Soft white cream.

7. REGISTRATION NUMBER:

29/20.2.2/0199

8. NAME AND ADDRESS OF REGISTRATION HOLDER:

Shanur Healthcare (Pty) Ltd

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9. DATE OF PUBLICATION

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