Read all of this leaflet carefully before you start taking POLYGYNAX® Vaginal capsules.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **POLYGYNAX®** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS **S4**

PRODUCT NAME strength pharmaceutical form

POLYGYNAX® (Each Vaginal Soft Capsule contains Neomycin Sulphate 35 000 IU / Polymixin B Sulphate 35 000 IU / Nystatin 100 000 IU)

What is in this leaflet

1. What **POLYGYNAX®** is and what it is used for
2. What you need to know before you use **POLYGYNAX®**
3. How to use **POLYGYNAX®**
4. Possible side effects
5. How to store **POLYGYNAX®**
6. Contents of the pack and other information

1. What POLYGYNAX® is and what it is used for

POLYGYNAX® is an antimicrobial agent. Antimicrobials are medicines used in the treatment of infections caused by bacteria and fungi. This medicine is a local anti-infectious vaginal capsule which combines 3 active substances:

- Two Antibiotics
- Neomycin which belongs to the aminoside family.
- Polymyxin B which belongs to the polypeptide family. They fight infections due to bacteria.
- An antifungal: Nystatin which belongs to the polyene family. It allows the destruction of some microscopic fungus or to block their growth.

POLYGYNAX® is indicated in the local treatment of vaginal infections.

2. What you need to know before you take POLYGYNAX®

Do not take POLYGYNAX®

- if you are allergic (hypersensitive) to one of the active substances (neomycin, polymyxin B or nystatin) or any of the other ingredients of **POLYGYNAX®**, listed in section 6.
- if you are allergic (hypersensitive) to medicine of the same family as neomycin (aminoglycosides), polymyxin B (polypeptides) or nystatin (polyenes).
- if you are allergic (hypersensitive) to peanut or soya as this medicine contains soybean oil.
- if you use diaphragms or latex condoms.

POLYGYNAX® is generally not recommended in combination with spermicidal products (local contraceptives) as it is likely to render the spermicide ineffective.

Warnings and precautions

Take special care with POLYGYNAX®

Talk to your doctor or pharmacist before using POLYGYNAX® vaginal capsule.

- If you have renal insufficiency, inform your doctor before using this medicine.

- Stop the treatment and inform your doctor if an allergic reaction occurs (see section 4).
- If you have an allergic reaction to POLYGYNAX®, the later use of the same antibiotic or related antibiotics by oral route may be compromised.

Children and adolescents

Not applicable.

Other medicines and POLYGYNAX®:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.) Do not use with spermicidal products (risk of inhibition) nor with condoms or diaphragms in latex (risk of rupture of the condom or diaphragm).

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Safety in pregnancy and breast-feeding has not been established.
The use of this medicine is not recommended in pregnancy. If you discover that you are pregnant during the treatment, consult rapidly your doctor as he only can adapt the treatment to your situation.

Driving and using machinery:

It is not always possible to predict to what extent **POLYGYNAX®** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **POLYGYNAX®** affects them.

3. How to take POLYGYNAX®

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

Dosage

Always take **POLYGYNAX®** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

FOR ADULTS ONLY

The usual dosage is one vaginal capsule in the evening for 12 days.

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

Method and route of administration

Vaginal route. Do not swallow.

The **POLYGYNAX®** Vaginal capsule should be inserted, preferably at night, into the vagina as deeply as possible. This is best achieved when lying back with the legs slightly drawn up.

Ensure good hygiene (wear cotton underwear, avoid vaginal douches, and avoid using an internal tampon during the treatment). Do not stop the treatment during menstruation periods.

Your doctor may also treat your sexual partner and this will be discussed by your doctor with you.

If you take more POLYGYNAX® than you should

An excessive and prolonged administration can cause adverse effects

on the hearing function and on kidneys in particular in patients with renal insufficiency. A prolonged use also leads to an increased risk of allergic eczema.

In the event of overdosage, consult your doctor or pharmacist. If neither is available,

contact the nearest hospital or poison control centre.

If you forget to take POLYGYNAX®

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

POLYGYNAX® can have side effects.

Not all side effects reported for **POLYGYNAX®** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **POLYGYNAX®**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **POLYGYNAX®** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- rash, hives (urticaria) or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **POLYGYNAX®**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Vaginal itching or irritation
- A burning sensation in the vaginal area
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effect, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **POLYGYNAX®**

5. How to store POLYGYNAX®:

Store at or below 25 °C.

Keep in original container until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use **POLYGYNAX®**, vaginal capsule after the expiry date which is stated on the outer carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

The active substances are Neomycin Sulphate 35 000 IU / Polymixin B Sulphate 35 000 IU and Nystatin 100 000 IU.

The other ingredients are: Tefose 63 (PEG-6 stearate and glycol stearate and PEG-32 stearate), hydrogenated soyabean oil, dimeticone 1 000.

Composition of the shell soft capsule: gelatine, glycerol, dimeticone 1000

Important information about some of the ingredients of POLYGYNAX®:

List of excipients with known effects: hydrogenated soybean oil.

What POLYGYNAX® looks like and contents of the pack

POLYGYNAX® Vaginal capsules are smooth, oval, pale yellow to yellow vaginal capsules.

POLYGYNAX® Vaginal capsules are packaged in PVC/PVDC/Aluminium blisters in packs of 6 or 12 capsules per blister. The blisters are placed in an outer cardboard carton.

HOLDER OF CERTIFICATE OF REGISTRATION:

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

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