

PATIENT INFORMATION LEAFLET (PIL) TEMPLATE

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

POLYGYNAX, vaginal capsule

Neomycin sulfate, Polymyxin sulfate, Nystatin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

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

1. WHAT POLYGYNAX, vaginal capsule IS AND WHAT IT IS USED FOR?

What POLYGYNAX, vaginal capsule is?

Pharmacotherapeutic group: ANTIINFECTIVES and ANTISEPTICS IN GYNECOLOGICAL USE (G. genitourinary system and sex hormones) – ATC code: G01AA51.

This medicine is a local anti-infectious. POLYGYNAX, vaginal capsule combines 3 active substances:

- Two antibiotics:
 - Neomycin which belongs to the aminoglycoside 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.

What it is used for?

This medicine is indicated for the local treatment of vaginal infections (vaginitis) sensitive to active substances contained in this medicine (neomycin, polymyxin B and nystatin).

This medicine is intended for adult only.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE POLYGYNAX, vaginal capsule?

Do not use POLYGYNAX, vaginal capsule:

- if you are allergic (hypersensitive) to one of the active substances (neomycin, polymyxin B or nystatin) or any of the other ingredients of this medicine, 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.

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

Warnings and precautions

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).

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- If you have an allergic reaction to this medicine, 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, vaginal capsule

This medicine should not be used with:

- spermicidal products (local contraceptives) as it risks rendering the spermicide ineffective,
- diaphragm or condoms in latex as there is a risk of rupture of the diaphragm or condom.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

POLYGYNAX, vaginal capsule with food, drink and alcohol

Not applicable.

Pregnancy and breast-feeding

Unless otherwise stated by your doctor, the use of this medicine is not recommended during pregnancy and breast-feeding. If you discover that you are pregnant during the treatment, consult rapidly your doctor as he only can adapt the treatment to your situation.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Not applicable.

POLYGYNAX, vaginal capsule contains hydrogenated soybean oil (see the paragraph above «Do not take POLYGYNAX, vaginal capsule»).

3. HOW TO USE POLYGYNAX, vaginal capsule?

Posology

- Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Always respect the prescribed dose and treatment duration as indicated by your doctor.
- The recommended dose is one capsule in the evening at bedtime for 12 days.

Method and route of administration

- This medicine should be used by vaginal route. Do not swallow the vaginal capsules.
- You should introduce the capsule deep into the vagina, preferably in lying down position. The easiest way to proceed is to lie on your back, knees folded up and opened.

Practical advice

In addition to your treatment, you are advised to follow some hygiene measures:

- In order not to contaminate your entourage, use your own bathroom linen (glove, towel).
- Wear cotton underwear.
- Avoid vaginal showers.
- Avoid the use of tampons during the treatment.
- Do not discontinue the treatment during menstruation periods.
- Your doctor may also treat your sexual partner.

If you take more POLYGYNAX, vaginal capsule 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.

If you forget to use POLYGYNAX, vaginal capsule

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

If you stop using POLYGYNAX, vaginal capsule

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you use this medicine for a prolonged period of time, an allergic reaction can appear. You will recognize it by the appearance of eczema (itchy red patches on the skin) locally or far from the treated area. If this effect occurs, you should immediately stop this treatment and inform your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Competent Authority for pharmacovigilance in your country.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE POLYGYNAX, vaginal capsule?

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What POLYGYNAX, vaginal capsule contains?

- The active substances are :

Neomycin sulfate 35 000 I.U.

Polymyxin B sulfate..... 35 000 I.U.

Nystatin 100 000 I.U.

For one vaginal capsule.

- The other ingredients are: PEG-6 stearate and glycol stearate and PEG-32 stearate (Tefose 63), hydrogenated soybean oil, dimeticone 1000.
- Composition of the shell soft capsule: gelatine, glycerol, dimeticone 1000.

What POLYGYNAX, vaginal capsule looks like and contents of the pack?

- This medicine is a vaginal capsule.
- Each box contains 6 or 12 vaginal capsules.

Marketing Authorisation holder

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL
FRANCE

Manufacturer

INNOTHERA CHOUZY
Rue René Chantereau, Chouzy-sur-Cisse
41150 VALLOIRE-SUR-CISSE
France

Name of the medicinal product in Member States of the European Union
Not applicable.

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Sanitary education advice:

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What to know about antibiotics?

Antibiotics are efficient in fighting against infections caused by bacteria. They are not efficient against infections caused by viruses.

Your doctor has chosen to prescribe you this antibiotic because it is suitable for you and it is fighting against your current illness. Bacteria are able to survive or to reproduce themselves despite the action of an antibiotic. This phenomenon is called resistance: it leads to inactivity of some antibiotic treatments.

Resistance is increased by abusive or inappropriate use of antibiotics. You may risk inducing the appearance of resistant bacteria and consequently delay your recovery or lead to the inactivity of this medicine if you do not respect:

- the dosage,
- the times of intakes,
- and the duration of treatment.

Consequently, in order to preserve the efficacy of this medicine:

- Use an antibiotic only when your doctor has prescribed it to you.
- Strictly follow your prescription.
- Never use again an antibiotic without medical prescription even if you think of treating a similar disease.
- You must never give your antibiotic to another person, it may not be adapted to their disease.
- After your treatment is finished, bring all the opened boxes back to your pharmacist for a proper and appropriate disposal of this medicine.