SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

POLYGYNAX® VIRGO, vaginal capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Neomycin sulfate.....35 000 IU
Polymyxin B sulfate.....35 000 IU
Nystatin.....100 000 IU
For one vaginal capsule.

Excipient with known effect: hydrogenated soybean oil.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vaginal capsule.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local treatment of vaginitis due to sensitive germs and treatment of non-specific vaginitis.
The official recommendations concerning appropriate use of antibacterial products must be taken into consideration.

4.2. Posology and method of administration

Posology
PARTICULARLY INTENDED FOR LITTLE GIRLS AND TEENAGER GIRLS.
One vulvo-vaginal instillation in the evening, after cleansing, for 6 consecutive days.

Method of administration
Instill the medicinal suspension in the vestibule and the vagina by pressing slowly on the capsule.

Practical advices
- The treatment should be associated with hygiene recommendations (wear cotton underwear, avoid using an internal tampon during the treatment...) and elimination of contributing factors as much as possible.
- Do not stop the treatment during menstrual periods.

4.3. Contraindications

This medicinal product is contraindicated in the following situations:
- In case of history of hypersensitivity to one of the components (or relevant group sensitivity),
- In case of use of diaphragms and latex condoms,
- In case of allergy to peanut or soya, due to the presence of soybean oil.

This medicinal product is generally not recommended in combination with spermicides.

4.4. Special warnings and precautions for use

Warnings:
In the event of local intolerance or allergic reaction, the treatment must be interrupted.
The sensitisation to antibiotics by local route may compromise its later use of the same antibiotic or related antibiotics using the systemic route.

Precautions for use:
The duration of treatment should be limited because of the risk of selecting resistant germs and superinfection by these germs.
In the absence of data on the importance of neomycin and polymyxin B fractions resorbed by the mucosa, the risk of systemic effects, especially increased with renal insufficiency, cannot be excluded.

This medicinal product contains soybean oil and may cause hypersensitivity reactions (urticaria, anaphylactic shock).

4.5. Interaction with other medicinal products and other forms of interaction

Contraindicated combination
+ Condoms and diaphragms
Risk of rupture.

Combination not recommended:
+ Spermicide
Any local vaginal treatment is likely to inactivate a spermicidal local contraception.

4.6. Fertility, pregnancy and lactation

Pregnancy
Due to the presence of an aminoside, neomycin, causing an ototoxic risk and the possibility of systemic absorption, the use of this medicinal product is not recommended during pregnancy.

Lactation
Due to the digestive immaturity of the newborn and pharmacokinetic properties of this medicinal product, its prescription is not recommended during lactation.

4.7. Effects on ability to drive and use machines

Not relevant.

4.8. Undesirable effects

Possibility of contact allergic eczema, this occurs more frequently with long-term use. These lesions may spread far from the treated areas.
The risk occurrence of toxic systemic effects (renal, hearing) is limited due to short-term treatment period recommended.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (Ansm - French Health Products Safety Agency) and Regional Pharmacovigilance Centers - Website: www.ansm.sante.fr.

4.9. Overdose

An excessive and prolonged administration could induce systemic effects (hearing and renal) in particular in patients with renal insufficiency. A prolonged use also exposes to an increased risk of allergic eczema.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: ANTIINFECTIVES AND ANTISEPTICS IN GYNECOLOGICAL USE (G. genito urinary system and sex hormones), code ATC: G01AA51.

Combination of neomycin, polymyxin B and nystatin.
Neomycin is an aminoside antibiotic.
Polymyxin B is a polypeptide antibiotic.
Nystatin is an antifungal with anticandida activity.

ANTIBACTERIAL ACTIVITY SPECTRUM OF POLYMYXIN B AND NEOMYCIN

POLYMYXIN B

Critical concentrations separate sensitive strains from strains with intermediate sensitivity and the latter from resistant ones:
$S \leq 2$ mg/l and $R > 2$ mg/l
The prevalence of acquired resistance may vary with the geographical location and time for certain species. It is therefore useful to have information on the prevalence of local resistance, in particular when treating severe infections. These data can only be used as an orientation for the probabilities of sensitivity of a bacterial strain to this antibiotic.

When the variability of the prevalence of resistance is known in France for a bacterial species, it is provided in the following table:

Categories	Frequency of acquired resistance in France (>10%) (limit values)
SENSITIVE SPECIES **Aerobic Gram-negative bacteria** *Acinetobacter* *Aeromonas* *Alcaligenes* *Citrobacter freundii* *Citrobacter Koseri* *Enterobacter* *Escherichia coli* *Klebsiella* *Moraxella* *Pseudomonas aeruginosa* *Salmonella* *Shigella* *Stenotrophomonas maltophilia*	**0 – 30%**
RESISTANT SPECIES **Aerobic Gram-positive bacteria** Cocci and bacilli **Aerobic Gram-negative bacteria** *Branhamella catarrhalis* *Brucella* *Burkholderia cepacia* *Burkholderia pseudomallei* *Campylobacter* *Chryseobacterium meningosepticum* *Legionella* *Morganella* *Neisseria* *Proteus* *Providencia* *Serratia* *Vibrio cholerae El Tor* **Anaerobic** Cocci and bacilli **Others** Mycobacteria	

NEOMYCIN

The prevalence of acquired resistance may vary with geographical location and time for certain species. It is therefore useful to have information on the prevalence of local resistance, in particular when treating severe infections. These data can only be used as an orientation for the probabilities of sensitivity of a bacterial strain to this antibiotic.

When the variability of the prevalence of resistance is known in France for a bacterial species, it is provided in the following table:

Categories	Frequency of acquired resistance in France (> 10%) (limit values)
SENSITIVE SPECIES	
Aerobic Gram-positive bacteria	
Corynebacterium	
Listeria monocytogenes	
Staphylococcus meti-S	
Aerobic Gram-negative bacteria	
Acinetobacter (essentially Acinetobacter baumanii)	50 – 75%
Branhamella catarrhalis	
Campylobacter	
Citrobacter freundii	20 – 25%
Citrobacter koseri	
Enterobacter aerogenes	?
Enterobacter cloacae	10 – 20%
Escherichia coli	15 – 25%
Haemophilus influenzae	25 – 35%
Klebsiella	10 – 15%
Morganella morganii	10 – 20%
Proteus mirabilis	20 – 50%
Proteus vulgaris	?
Providencia rettgeri	?
Salmonella	?
Serratia	?
Shigella	?
Yersinia	?

Categories	Frequency of acquired resistance in France (>10%) (limit values)
MODERATELY SENSITIVE SPECIES (*in vitro* of intermediate sensitivity) **Aerobic Gram-negative bacteria** *Pasteurella*	
RESISTANT SPECIES **Aerobic Gram-positive bacteria** Enterococci *Nocardia asteroides* *Staphylococcus meti-R** *Streptococcus* **Aerobic gram negative bacteria** *Alcaligenes denitrificans* *Burkholderia* *Flavobacterium sp.* *Providencia stuartii* *Pseudomonas aeruginosa* *Stenotrophomonas maltophilia* **Anaerobic** Strictly anaerobic bacteria **Others** *Chlamydia* Mycoplasma Rickettsies	

*The frequency of resistance to methicillin is approximately 30 to 50% of all staphylococci and is encountered mainly in hospitals.

Remark: these spectra correspond to those of the systemic forms of these antibiotics. With local pharmaceutical presentations, concentrations obtained *in situ* are much higher than plasma concentrations. There is some remaining uncertainty concerning kinetics of *in situ* concentrations, local physicochemical conditions which can alter the antibiotic activity and product stability *in situ*.

5.2. Pharmacokinetic properties

Not provided.

5.3. Preclinical safety data

Not provided.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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, residual purified water.

6.2. Incompatibilities

Not relevant.

6.3. Shelf-life

2 years.

6.4. Special precautions for storage

Do not store above 30°C.

6.5. Nature and contents of container

6 capsules under blister (PVC/PVDC/Aluminium).

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22, Avenue Aristide Briand
94 110 ARCUEIL

8. MARKETING AUTHORISATION NUMBER(S)

03935/4872/NMR/2017

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: Jul 11, 2019
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

September 16th, 2016

11. DOSIMETRY

Not applicable.

12.INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.