

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of medicinal product

PHARMATEX 18.9 mg, pessaries

Benzalkonium chloride

Text box

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 PHARMATEX 18.9 mg, pessaries is and what it is used for
2. What you need to know before you use PHARMATEX 18.9 mg, pessaries
3. How to use PHARMATEX 18.9 mg, pessaries
4. Possible side effects
5. How to store PHARMATEX 18.9 mg, pessaries
6. Contents of the pack and other information

1. What PHARMATEX 18.9 mg, pessaries is and what it is used for

What PHARMATEX 18.9 mg, pessaries is

Pharmacotherapeutic group: CONTRACEPTIVE FOR LOCAL USE (G : genitourinary system) – ATC code : G02BB.

This medicine is a local contraception:

- It contains a spermicide (chemical substance that destroys spermatozooids)
- It reduces the risk of pregnancy without totally eliminating it. **Efficacy depends on respecting the instructions for use.**

When to use PHARMATEX 18.9 mg, pessaries

This local contraception method may be used by all women who require contraception and especially:

- if you cannot use an hormonal contraception (see section 6) or an intra-uterine device (IUD), also called coil.
- if you have just delivered, if you breastfeed or if you are in premenopausal period.
- if you wish an episodic contraception.
- as an adjuvant to contraception by a diaphragm, a cervical cap or a IUD (especially if you take long-term treatment with certain medicines, such as Non-Steroidal Anti-Inflammatory Drugs).
- if you have forgotten to take a tablet of your oral contraception or if you have taken your tablet with delay.

In those cases, read again the package leaflet of your oral contraception and combine both methods of contraception during the rest of the menstrual cycle.

2. What you need to know before you use PHARMATEX 18.9 mg, pessaries

Do not use PHARMATEX 18.9 mg, pessaries

if you are allergic to benzalkonium chloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using PHARMATEX 18.9 mg, pessaries.

- Before you use PHARMATEX be sure to read carefully its method of administration and to understand it.
- Systematically place PHARMATEX high into the vagina before each intercourse, regardless of your menstrual cycle period.
- Soapy water destroys the active substance of this local contraception. Therefore, you should not wash private parts with soap 2 hours before and 2 hours after the intercourse. Only external washing with pure water is possible for both partners.
- Should you want to douche with pure water, wait for at least 2 hours.
- Avoid taking a bath, swimming in the sea or in a pool because it may be reduce the efficacy of PHARMATEX.
- If a genital lesion develops or worsens, stop the treatment and consult your doctor.
- If a vaginal treatment or any other product used by vaginal route is necessary, wait until this treatment is completed before starting (again) the contraception with PHARMATEX.

Warning: This method of contraception does not protect against sexually transmitted diseases, nor against AIDS. To date, only the associated condom provides a real protection.

Why it is so important to closely follow the instructions for use

This local contraception method is less efficient than other contraception methods, such as:

- hormonal contraception: oral contraception, subcutaneous implant, contraceptive patch, hormone-releasing IUD, vaginal ring,
- copper IUD
- diaphragm, cervical cap,
- condom.

Therefore it is very important that your doctor or pharmacist explains you precisely the instructions for use.

If you have not understood how to use this medicine, do not hesitate to ask again your doctor or pharmacist.

It is important to strictly conform to the instructions for use for getting the most possible efficient contraception.

Use one pessary **systematically before each intercourse**, regardless of your cycle period, even during menstrual periods.

Children

Not applicable.

Other medicines and PHARMATEX 18.9 mg, pessaries

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- It is generally not recommended to use PHARMATEX at the same time as other medicines with vaginal administration or soaps. Indeed they may make PHARMATEX lose its contraceptive efficacy.
- If your doctor has prescribed you a vaginal treatment, wait until the end of that treatment before using PHARMATEX.
- You can use a condom with PHARMATEX to ensure a higher protection.

PHARMATEX 18.9 mg, pessaries with food and drink

Not applicable.

Pregnancy and breast-feeding

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 taking this medicine.

The use of PHARMATEX at the beginning of an unknown pregnancy does not expose to particular risk for the foetus.

Breast-feeding is possible.

Driving and using machines

Not applicable.

PHARMATEX 18.9 mg, pessaries, contains

Not applicable.

3. How to use PHARMATEX 18.9 mg, pessaries

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

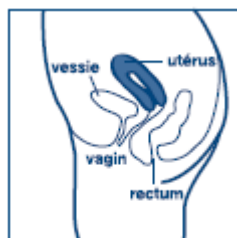
- Systematically use one pessary before each intercourse, regardless of your cycle period, even during menstrual periods.
- In case of repeated acts of intercourse, use an additional pessary before each new act.

Route and method of administration

This medicine is used by vaginal route. Do not swallow it.

The following conditions should be strictly respected as **efficacy depends on respecting the instructions for use**:

- Systematically place one pessary high into the vagina 5 minutes before each intercourse, regardless of your cycle period, even during menstrual periods.
- Preferably place the pessary in lying down position, to allow the application high into the vagina.
- Place another pessary before each intercourse in case of repeated acts of intercourse.
- The duration of protection is 4 hours.
- Immediately before or after intercourses, only external washing with pure water is possible for both partners. Do not wash private parts with soap.



If you use more PHARMATEX 18.9 mg, pessaries than you should

Tell immediately your doctor or pharmacist.

If you forget to use PHARMATEX 18.9 mg, pessaries

There is a risk of pregnancy. In this case, emergency contraception can be used, it must be taken as soon as possible. (see also section 6. Notions on the menstrual cycle and contraception).

If you stop using PHARMATEX 18.9 mg, pessaries

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.

Rare side effects (affecting between 1 and 10 patients in 10 000)

- Itching, burning sensations or local irritations in one or both partners

Side effects of unknown frequency (cannot be estimated from the available data)

- allergy to one of the ingredients of the medicine.
You will recognise the signs of an allergy by redness, itching, and very rarely a sudden swelling of the neck and face that results in difficulty breathing. If those signs develop, immediately consult 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 national reporting system: French National Agency for Medicines and Health Products Safety (ANSM) and the network of Regional Pharmacovigilance Centres – Website: www.ansm.sante.fr.

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

5. How to store PHARMATEX 18.9 mg, pessaries

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 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 protect the environment.

6. Contents of the pack and other information

What PHARMATEX 18.9 mg, pessaries contains

- The active substance is:
Benzalkonium chloride 18.9 mg
In the form of aqueous solution of benzalkonium chloride at 50% (w/v) 37.8 mg

For one soft vaginal pessary.

- The other ingredients are:
Hydroxypropylcellulose and solid hemisynthetic glycerides (type Witepsol S51).

What PHARMATEX 18.9 mg, pessaries looks like and contents of the pack

This medicine is presented as pessary. Box of 10 or 20.

Marketing Authorisation Holder

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL

Operator

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND

94110 ARCUEIL

Manufacturer

INNOTHERA CHOUZY
RUE RENE CHANTEREAU, CHOUZY-SUR-CISSE
41150 VALLOIRE-SUR-CISSE

Name of the medicine in the Member States of the European Union

Not applicable.

This leaflet was last revised in

December 2017

Other sources of information

Detailed information on this medicine is available on the ANSM web site (France).

NOTIONS ON THE MENSTRUAL CYCLE AND CONTRACEPTION

What is the menstrual cycle?

- The menstrual cycle is the time elapsed between the first day of periods and the beginning of the next periods.
- The average length of a cycle is 28 days but it can significantly vary from one woman to another.
- Periods occur when a woman is not pregnant.

What is ovulation, and when does it occur?

- Ovulation is the time when an ovary releases an ovule that is received by the uterine tube
- Ovulation generally occurs in the middle of the cycle but it can occur at any time of the cycle, even during the periods.

When does pregnancy begin?

- If spermatozoids are located close to the ovule in the uterine tube, "fertilisation" (i.e. the meeting of the ovule and a spermatozoid to create an embryo) can take place.
- After a few days, the fertilised ovule will fix itself (or "implant") in the uterus and pregnancy begins.

What are the main contraceptive methods?

- The hormonal contraception: oral contraception, subcutaneous implant, contraceptive patch, hormone-releasing intrauterine device (IUD), vaginal ring.
- The copper IUD.
- The local contraception: spermicides, condoms, diaphragms, cervical caps.
- The female sterilisation.

What are the means to protect against sexually transmitted diseases (STD), HIV infection and AIDS included?

If properly used, the male or female condom is the only mean to protect against STD and Human Immunodeficiency Virus (HIV), responsible for AIDS (Acquired Immune Deficiency Syndrome). The other contraceptive methods do not protect against Sexually Transmitted Diseases nor against AIDS.

What to do in case of unprotected intercourse, or if I forget to take my usual contraception?

If you are in this situation, ask quickly your doctor or pharmacist for advice.

- You can use emergency contraception (also called morning-after pill). It must be used as soon as possible.
- This kind of contraception aims to prevent from pregnancy by blocking or delaying ovulation.

What to do if your situation changes, or if this contraceptive method does not or no longer suit you?

Consult your doctor, he can prescribe you a different and more appropriate contraceptive method.