ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PHARMATEX 18.9 mg, pessaries

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzalkonium chloride .....18.9 mg

In the form of aqueous solution of benzalkonium chloride at 50% w/v .....37.8 mg

For one pessary.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pessary.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local contraception: this method reduces the risk of pregnancy without totally eliminating it.

Efficacy depends on respecting the instructions for use.

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

- if there is a temporary or permanent contraindication for hormonal contraception or the intra-uterine device (IUD);
- after giving birth, during breast-feeding, during premenopause;
- when episodic contraception is required ;
- as an adjunct to local contraception using vaginal plug (diaphragm, cervical cap) or IUDs (especially in the case of long-term treatment with certain medicines, such as NSAIDs) ;
- when an additional local contraceptive method is recommended in situations where an oral contraception intake is forgotten or delayed. In this case, combine the two methods of contraception throughout the rest of the menstrual cycle.

4.2. Posology and method of administration

Posology

Systematic use before each intercourse, regardless of the cycle period.

Method of administration

Vaginal route.

In lying down position, place the pessary high into the vagina 5 minutes before each intercourse.

In the event of repeated acts of intercourse, place another pessary.

The duration of protection is 4 hours.

Immediately after intercourses, only external washing with pure water is possible.

4.3. Contraindications

This medicinal product **should never be used** in case of hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4. Special warnings and precautions for use

If used properly with every act of sexual intercourse, PHARMATEX is effective in decreasing the risk of pregnancy. However, this local contraception method is less efficient than hormonal contraception, intrauterine device, diaphragm, cervical cap and condom.

Contraceptive efficacy depends essentially on its correct use. Therefore, it is important to accurately explain the instructions for use to the patient and ensure they are properly understood.

This type of contraception should be avoided by any person who can neither understand nor accept it.

If this type of contraception is used in case a forgotten or delayed oral contraception intake, it is recommended to explain again to the patient the need to continue her usual oral contraception.

The following conditions must be respected:

- systematically place a pessary high into the vagina before intercourses, regardless of the cycle period;
- do not use soap for washing genitals 2 hours before and 2 hours after the intercourse, as soapy water, even in trace amounts, destroys the active substance. Only external washing with pure water is possible for both partners ;
- should the user want to douche with pure water, wait for at least 2 hours as it risks eliminating the product ;
- avoid taking a bath, swimming in the sea, in a pool or another because the contraceptive action may be reduced ;
- Stop the use of PHARMATEX if a genital lesion develops or worsens ;
- in the case of treatment by vaginal route, wait until the end of said treatment before using PHARMATEX. Another method of contraception will therefore be advised.

This method of contraception does not protect against sexually transmitted infections (STIs) or against the Human Immunodeficiency Virus (HIV), which causes AIDS (Acquired Immune Deficiency Syndrome). Used correctly during sexual intercourse, condom (male or female) is the only contraceptive that also protects against STIs and HIV / AIDS.

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

Combinations not recommended

\+ **Medicinal products with vaginal administration**

Any local vaginal treatment is likely to inactivate local spermicidal contraception.

\+ **Soaps**

This spermicide is destroyed by soaps: avoid any washing with soap because soap, even in trace amounts, destroys the active substance.

A compatibility study between the pessary and latex, conducted with various trademarks of condoms, have not shown any damage in the physical characteristics of the tested condoms.

4.6. Fertility, pregnancy and lactation

Pregnancy

Clinically, epidemiological studies have not revealed any malformation effect linked to accidental use of this spermicide in early pregnancy.

Breast-feeding

Very small quantities may pass into maternal milk, without any known harmful consequences. Breast-feeding is possible.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

The undesirable effects reported with PHARMATEX during post marketing experience are listed below, by system organ class and frequency using the following categories: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1 000 to <1/100), rare (≥ 1/10 000 to <1/1 000), very rare (<1/10 000), not known frequency (cannot be estimated from the available data).

Reproductive system and breast disorders

Rare: itching, burning sensations or local irritations in one or both partners.

Immune system disorders

Not known frequency: possibility of allergy.

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: The Agence nationale de sécurité du médicament et des produits de santé (Ansm - National Agency of Medicine and Health Products Safety) and the network of Regional Pharmacovigilance Centers - Website: www.ansm.sante.fr

4.9. Overdose

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: CONTRACEPTIVE FOR LOCAL USE (G : genito urinary system), ATC code : G02BB.

Benzalkonium chloride is both a spermicide and an antiseptic.

The active substance causes the rupture of spermatozoid membrane. The spermatozoid destruction takes place in two stages: first the flagellum is destroyed, then the head bursts.

The efficacy of the method varies according to how strictly the instructions are observed and the accuracy of the dialogue leading to prescription.

Saprophytic flora is not altered: Döderlein Bacillus is preserved.

Not being of a hormonal nature, Pharmatex does not affect the menstrual cycle, libido, fertility.

Based on experimental data, benzalkonium chloride also has antiseptic activity:

- *in vitro,* the product is active on a number of infectious agents responsible for sexually transmitted diseases, especially*: Neisseria gonorrhoeae, Chlamydia spp., Herpes simplex* type 2, HIV, *Trichomonas vaginalis, Staphylococcus aureus*. However, it has no activity on *Mycoplasma spp*. and low activity on *Gardnerella vaginalis*, *Candida albicans*, *Haemophilus ducreyi* and *Treponema pallidum* ;
- *in vivo*, some elements specify a possible activity in the prevention of certain sexually transmitted diseases, with no direct evidence of this preventive action.

5.2. Pharmacokinetic properties

The absorption of benzalkonium chloride by the vaginal mucosa is very low.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity , genotoxicity, carcinogenic potential, toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Hydroxypropylcellulose, solid hemisynthetic glycerides (type Witepsol S51).

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Do not store above + 25°C.

6.5. Nature and contents of container

Blister pack (PVC/Low-density polyethylene) of 5 pessaries.

Box of 10 or 20 pessaries.

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL

8. MARKETING AUTHORISATION NUMBER(S)

- 322 491-2: 10 pessaries in a blister pack (PVC/Low-density polyethylene)
- 320 550-1: 20 pessaries in a blister pack (PVC/Low-density polyethylene)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 11 February 1997

Date of latest renewal: 11 February 2007

10. DATE OF REVISION OF THE TEXT

01 December 2017

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.