

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Preventex Ovule 18.9 mg Pessary

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzalkonium chloride 18.9mg per pessary.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pessary
White, odourless pessaries.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the control of conception.

4.2 Posology and method of administration

Intravaginal use.

Insert a pessary as deeply as possible in the vagina at least 5 minutes before intercourse at all times during the cycle. It is easier to do this while lying down. Wait at least 5 minutes until the pessary is completely melted. Once melted, it provides protection for 4 hours. Should intercourse begin again, insert another pessary. External washing is possible immediately after intercourse, but using pure water only.

4.3 Contraindications

- Hypersensitivity to Benzalkonium chloride or to quaternary ammonium compounds.
- Do not use Preventex® Ovule pessary along with other vaginal medicines or hygiene products (see section 4.5.).

4.4 Special warnings and precautions for use

- In case of allergic reaction to Benzalkonium chloride, stop using the pessary immediately.
- Interrupt the treatment in case of genital lesions because of the presence of Benzalkonium chloride.
- As the efficacy depends on the careful compliance with the instructions for use, the following precautions should be stressed :
 - Use a pessary before intercourse at all times of the cycle.
 - It is easier to insert the pessary deeply in the vagina while lying down.
 - Wait at least 5 minutes until the pessary is completely melted.
 - Should intercourse begin again, insert another pessary.

- This pessary should not be used :
 - in association with soaps because they destroy the active substance, even in trace concentrations;
 - in association with intravaginal treatments in order to avoid interactions (see section 4.5.).
- This product should not be recommended to women who do not understand the precautions for use.

4.5 Interaction with other medicinal products and other forms of interaction

- Benzalkonium chloride is a cationic surfactant which is inactivated by anionic substances such as soaps, even in trace concentrations. Therefore, washing and vaginal douches containing soaps are contra-indicated before and after intercourse. External washing is possible immediately after intercourse, but using pure water only. Additional use of another substance is contra-indicated so as to prevent unfavourable cross-reactions.
- Intravaginal treatments must be stopped before beginning contraception with Preventex® Ovule pessary so as to prevent unfavourable cross-reactions.

4.6 Fertility, pregnancy and lactation

- **Pregnancy** : No risk due to the utilization of this spermicide at the beginning of pregnancy was observed. The teratological studies of the finished product and of Benzalkonium chloride itself yielded negative results. Studies have shown that Benzalkonium chloride does not enter the bloodstream.
- **Lactation** : Studies have shown the lack of diffusion of Benzalkonium chloride into the blood and milk of nursing mothers.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Possible allergy to Benzalkonium chloride.

4.9 Overdose

No case of overdose has been reported.

Note : The lethal dose of Benzalkonium chloride corresponds to the theoretical ingestion of several hundreds of pessaries. Thus the possibility of accidents through ingestion in humans can be excluded.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Local contraceptive. Group G : genito-urinary tract. ATC code : unknown.

Benzalkonium chloride has both potent spermicidal and antiseptic properties.

The pessary dissolves and covers the vaginal cavity with a protective film, the viscosity of which slows down the spermatozoa. The spermatozoa are destroyed in two stages : first destruction of the flagellum, then bursting of the head.

The clinical efficacy is assessed by a corrected Pearl Index lower than 1 if the product is properly used.

The efficacy of the method varies according to the compliance with the indications and precautions for use and to the quality of the dialogue before prescription.

The saprophytic vaginal flora (Doderlein bacillus) and pH are respected.

5.2 Pharmacokinetic properties

Benzalkonium chloride is a cationic surfactant. Therefore it is not *absorbed*. Studies have shown the lack of diffusion of Benzalkonium chloride into the blood and milk of women using this spermicidal agent. It is only *adsorbed* on the vaginal wall and will be eliminated with water or by the physiological flow.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, toxicity to reproduction.

The teratological studies of the finished product and of Benzalkonium chloride itself yielded negative results. (See section 4.6.).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Solid semi-synthetic glycerides (Witepsol S51)

6.2 Incompatibilities

Benzalkonium chloride is a cationic surfactant which is inactivated by anionic substances such as soaps, even in trace concentrations. (See section 4.5.).

Therefore, this medicinal product must not be mixed with other vaginal medicinal products or hygiene products such as soaps.

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

The pessaries are packed in blisters of polyvinylchloride laminated with polyethylene.

Package size : Box of 10 pessaries.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Aromapharm Ireland Ltd.
Regus House
Harcourt Road
Dublin 2

8 MARKETING AUTHORISATION NUMBER

PA 1164/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 November 2005

Date of last renewal: 04 November 2010

10 DATE OF REVISION OF THE TEXT

March 2012