

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pharmatex 18.9 mg Ovule

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ovule contains 18.9 mg of benzalkonium chloride.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Pessary

White odourless cylindrical pessary, with conical head.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

(a) Properties

Ovule containing benzalkonium chloride, which is a quaternary ammonium disinfectant and spermicidal agent.

(b) Indications for use

As an adjunct in the control of conception.

4.2 Posology and method of administration

Intravaginal.

One ovule should be inserted intravaginally at least 10 minutes prior to each coitus.

4.3 Contraindications

Use in patients with a known hypersensitivity to benzalkonium chloride.

4.4 Special warnings and precautions for use

1. If irritation of vagina or penis occurs the use of product should cease.
2. The product should only be recommended to individuals who understand the appropriate use of the agent.

4.5 Interaction with other medicinal products and other forms of interaction

The spermicide is inactivated by soap and other anionic surfactants even in trace amounts. Bathing or swimming must be avoided as the efficacy of the product is affected.

4.6 Pregnancy and lactation

As benzalkonium chloride is not absorbed, and as diffusion does not occur into the blood or milk of nursing mothers,

nor into the uterine cavity of animals, the use of Pharmatex Ovule in pregnancy or lactation is not contra-indicated.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Possibility of allergy.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylcellulose
Witepsol S51 (semi-synthetic glycerides)

6.2 Incompatibilities

Soap and other anionic surfactants even in trace amounts inactivate this spermicide. Bathing or swimming must be avoided as the efficiency of the product is affected.

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

10 or 20 Pharmatex ovules in 2 or 4 strips of 5 ovules in a thermoformed blister (PVC / low density Polyethylene) in a cardboard box with an insert leaflet.

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

If the ovules have melted because of the heat, place them in a fridge or under cold water, pointed downwards. They will recover their initial form without any alteration of the product.

7 MARKETING AUTHORISATION HOLDER

Innothera Ireland Ltd
Donaghcumper
Celbridge
Co. Kildare

8 MARKETING AUTHORISATION NUMBER

PA 334/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 December 1983

Date of last renewal: 06 December 2003

10 DATE OF REVISION OF THE TEXT

March 2005