# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Pharmatex 1.2% Vaginal Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzalkonium Chloride 1.2% w/w.

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Cream
Unctuous white vaginal cream with an odour of lavender.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

(a) Properties
Cream 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.

**Unidose**:

The contents of the container should be expelled as deeply as possible into the vagina using the nozzle and exerting sufficient pressure to the walls of the tube to ensure emptying of the contents. Protection is immediate and lasts for 4 hours.

**Multidose:**

The contents of the container should be expelled as deeply as possible into the vagina using the nozzle and crossbar of the device to ensure adequate distribution. Protection is immediate and lasts for 4 hours.

### 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 Cream 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

Citric acid anhydrous
Tefose ® 63 (Macrogol 300 and 1500 and ethyleneglycol stearate)
Essential oil of Lavender
Disodium phosphate dodecahydrate
Purified water

## 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

Multi-dose Tubes: 3 months.

Unit-dose Tubes:  6 months.

## 6.4 Special precautions for storage

Do not store above 25ºC.

## 6.5 Nature and contents of container

Multidose: varnished aluminium tube fitted with a low density polyethylene applicator, containing 72 g of cream.

Unit dose: low density polyethylene tube containing 4.5g of cream, 6 tubes in each carton.

## 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

Innothera Ireland Limited
Donaghcumper
Dublin Road
Celbridge
Co. Kildare

## 8 MARKETING AUTHORISATION NUMBER

PA 334/1/2

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 November 1983

Date of last renewal: 30 November 2003

## 10 DATE OF REVISION OF THE TEXT

May 2006