

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Betadine Vaginal Cleansing Kit.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Povidone Iodine 10% w/v

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Concentrate for vaginal solution

A dark brown coloured solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As an antiseptic for use in the management of pre-operative disinfection of vaginitis due to organisms sensitive to the iodine and in pre-operative preparation of the vagina.

##### 4.2 Posology and method of administration

For intravaginal administration.

Betadine Vaginal Cleansing concentrate should be diluted 1:10 and used according to the patient instruction leaflet provided.

Use once a day (preferably in the morning) for 14 consecutive days. If menstruation occurs during the treatment it is important to continue treatment during the days of the period.

##### 4.3 Contraindications

1. Use in patients hypersensitive to iodine.
2. Use in pregnancy.
3. Regular use is contraindicated in patients and users with thyroid disorders (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis).
4. Use in pre-pubertal children

##### 4.4 Special warnings and special precautions for use

1. If local irritation, redness or swelling develops discontinue treatment. Iodine is absorbed from the vagina and following prolonged use, thyroid dysfunction may develop. The product may be spermicidal and should not be used when conception is desired.
2. If no improvement occurs the doctor should be consulted.
3. Special caution is needed when regular applications to inflamed or broken vaginal mucosa are made to patients with pre existing renal insufficiency.

4. Regular use should be avoided in patients on concurrent lithium therapy.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

1. Absorption of iodine from povidone iodine through either intact or damaged skin may interfere with thyroid function tests.
2. Contamination with povidone iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false positive results.

#### **4.6 Pregnancy and lactation**

As with other douches, this product is not recommended during pregnancy.

#### **4.7 Effects on ability to drive and use machines**

None stated

#### **4.8 Undesirable effects**

Local irritation, redness or swelling may occur.

Anaphylactic reactions, anaphylactoid reactions and anaphylactic shock have been reported uncommonly with products containing povidone-iodine or povidone.

#### **4.9 Overdose**

Excess iodine can produce goitre and hypothyroidism or hyperthyroidism. In the case of accidental ingestion of large quantities of Betadine, symptomatic and supportive treatment should be provided with special attention to electrolyte balance and renal and thyroid function.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Povidone-iodine is a complex of iodine which shows all the broad spectrum germicidal activity of elemental iodine. The germicidal activity is maintained in the presence of blood, pus, serum and necrotic tissue. It is effective in the treatment of infections caused by bacteria, fungi, yeasts and viruses (e.g. Herpes Virus Types I and II).

#### **5.2 Pharmacokinetic properties**

None stated

#### **5.3 Preclinical safety data**

None stated

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Nonoxinol 9  
Fleuroma Bouquet 477  
Purified Water

## **6.2 Incompatibilities**

Compatibility with barrier contraceptives has not been established. Therefore, this product should not be used with such methods of contraception as their reliability may be affected.

## **6.3 Shelf Life**

Three years.

## **6.4 Special precautions for storage**

Store below 25°C.

## **6.5 Nature and contents of container**

250ml high density polyethylene bottle appropriately sealed with a measuring cup, and accompanied by an empty turquoise low density polyethylene squeeze bottle with vaginal applicator.

## **6.6 Instructions for use and handling**

The Betadine Vaginal Cleansing concentrate should be diluted 1:10 and used according to the patient instruction leaflet provided.

Once diluted, the colour of the solution is clear yellow-brown.

## **7 MARKETING AUTHORISATION HOLDER**

Seton Healthcare Group plc  
Tubiton House  
Oldham  
OL1 3HS  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 696/2/20

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

Date of first authorisation: 1<sup>st</sup> April 1993

Date of last renewal: 1<sup>st</sup> April 2003

## **10 DATE OF REVISION OF THE TEXT**

November 2004