

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Betadine Vaginal Pessaries.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Povidone Iodine 200mg

For excipients see section 6.1

#### 3 PHARMACEUTICAL FORM

Pessary

Smooth dark-brown in colour and tapered.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As an antiseptic in the management of vaginitis due to organisms sensitive to iodine and in pre-operative vaginal preparation

##### 4.2 Posology and method of administration

For intravaginal administration.

Using the applicator, insert a pessary morning and night for up to 14 days. Each pessary should be wetted with water immediately prior to insertion, thus ensuring maximum dispersion of the active constituent and avoiding risk of local irritation.

If menstruation occurs during treatment, it is important to continue treatment during the days of the period.

##### 4.3 Contraindications

1. Known or suspected iodine hypersensitivity.
2. Regular use is contraindicated in patients and users with thyroid disorders (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis).
3. 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

Regular use of povidone-iodine should be avoided in pregnant or lactating women as absorbed iodine can cross the placental barrier and can be secreted into breast milk. Although no adverse effects have been reported from limited use, caution should be recommended and therapeutic benefit must be balanced against possible effects of the absorption of iodine on foetal thyroid function and development.

## 4.7 Effects on ability to drive and use machines

None stated

## 4.8 Undesirable effects

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.

## 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

Macrogol 1000

## **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**

Strips of aluminium foil laminated to polyethylene or pre-formed PVC packaging with a polyethylene lining containing 28 pessaries. The strips are packaged in a carton.

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

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Seton Healthcare Group plc  
Tubiton House  
Oldham  
OL1 3HS  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 696/2/19

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

Date of first authorisation: 1<sup>st</sup> April 1983

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

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

April 2005