

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Micolette Micro-Enema Rectal Solution

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:	Sodium lauryl sulphoacetate	45.00	mg
	Sodium citrate	450.00	mg
	Glycerol	625.00	mg
Excipients:	Potassium sorbate (E202)	6.20	mg/5ml

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Rectal Solution  
Translucent, gel-like solution

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

For evacuation of the colon in constipation, prior to surgical and diagnostic procedures and in obstetrics prior to delivery.

#### 4.2 Posology and method of administration

Route of administration: Rectal

Adults and children aged 3 years and over:

Lubricate the nozzle with one drop of the contents; insert full length of nozzle into the rectum and squeeze tube until total contents have been administered.

Two tubes may be necessary in severe cases. When used in children the nozzle should be inserted to half its length only.

Children under 3 years of age: Not recommended.

Elderly: There are no special requirements for elderly patients but as with all medicines the lowest effective dose should be used.

#### 4.3 Contraindications

Inflammatory or ulcerative bowel disease. Acute gastrointestinal conditions.

#### 4.4 Special warnings and precautions for use

Excessive use of Micolette micro-enema may cause diarrhoea and fluid loss. In such cases, Micolette should be discontinued and appropriate therapy instituted.

The product should not be used in children under 3 years old.

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

Prolonged use may interfere with the absorption of some vitamins.

#### **4.6 Fertility, pregnancy and lactation**

Should only be used under medical supervision.

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

Not applicable.

#### **4.8 Undesirable effects**

Very occasionally, a slight cramp may occur. Prolonged use may lead to irritation of the anal canal.

#### **4.9 Overdose**

Not applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Sodium citrate is a 'peptizing' agent which liberates water present in the faeces. Sorbitol enhances this action. Sodium lauryl sulphoacetate is a wetting agent. Glycerol promotes peristalsis and evacuation of the lower bowel

#### **5.2 Pharmacokinetic properties**

Not applicable.

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

Not applicable.

### **6 PHARMACEUTICAL PARTICULARS**

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

Liquid sorbitol (non-crystallising)  
Potassium sorbate (E202)  
Purified water

#### **6.2 Incompatibilities**

Not applicable

#### **6.3 Shelf life**

2 years

#### **6.4 Special precautions for storage**

Do not store above 25°C.

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

Disposable low density polyethylene tube with nozzle and removable cap.  
Pack size: 12 x 5ml tubes.

#### **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**

Pinewood Laboratories Limited  
Ballymacarbry  
Clonmel  
County Tipperary

### **8 MARKETING AUTHORISATION NUMBER**

PA0281/115/001

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

Date of first authorisation: 26 November 1991  
Date of last renewal: 26 November 2006

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

February 2007