

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

FLETCHERS' ENEMETTE

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml enema contains 90.0g Docusate Sodium BP and 3.78gm Glycerol Ph.Eur.

## 3 PHARMACEUTICAL FORM

Rectal solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Routine treatment of constipation. Pre-and post-operative cleansing of the bowel, in obstetrics and prior to proctoscopy, sigmoidoscopy or X-ray examination.

### 4.2 Posology and method of administration

Adults including the elderly:

1 enema as required

Children over 3 years of age:

As for adults.

Children under 3 years of age:

Not recommended.

Remove cap and squeeze out a drop of liquid to lubricate the nozzle. Insert the full length of the nozzle into the rectum and squeeze the tube until the whole contents have been administered. Withdraw the nozzle still squeezing the tube.

When administering to young children the nozzle should only be inserted to half its length into the rectum.

#### **4.3 Contraindications**

None known.

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

Use with caution in patients with intestinal obstruction. Care should be taken not to use undue force in administration of the enema especially in the elderly or debilitated patients or those with neurological disorders.

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

None known.

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

No special warnings.

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

None known.

#### **4.8 Undesirable effects**

None known.

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

Not observed.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Docusate sodium is used as a faecal softening agent in the management of constipation. It is an anionic surfactant considered to act by stimulating intestinal secretions of water and electrolytes and by increasing the penetration of fluid into the faeces. It may also have a stimulant laxative effect.

Glycerol is classified as a hyperosmotic laxative and usually acts within 15-30 minutes following rectal administration. Its action is possibly due to hygroscopic or osmotic effects of glycerol drawing water into the faeces promoting rectal contraction. Glycerol may act additionally or alternatively through its local irritant effects, it may also have lubricating and faecal softening actions. (Martindale 30<sup>th</sup> edition)

#### **5.2 Pharmacokinetic properties**

Docusate salts when administered orally are absorbed from the gastro-intestinal tract and excreted in bile.

Glycerol when administered orally is absorbed from the gastro-intestinal tract and undergoes extensive metabolism, especially in the liver. It may also be excreted in the urine unchanged. (Martindale 30<sup>th</sup> edition)

**5.3 Preclinical safety data**

None stated.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Polyethylene glycol 400 NF and Sorbic acid BP.

**6.2 Incompatibilities**

None known.

**6.3 Shelf life**

24 months.

**6.4 Special precautions for storage**

Store below 25°C.

**6.5 Nature and contents of container**

White or light blue LDPE tubes with elongated nozzles sealed with a push-on closure of the same material.

## **6.6 Special precautions for disposal**

Fletchers' Enemette may be warmed before use by placing in warm water but do not heat to a temperature greater than 25°C (approximately 80°F).

To administer remove the cap and squeeze out a drop of liquid to lubricate the nozzle. Insert the full length of the nozzle into the rectum and squeeze the tube until all the contents are administered. Take out while still squeezing the tube and discard the tube hygienically.

When administering to young children the nozzle should only be inserted to half its length into the rectum.

## **7 MARKETING AUTHORISATION HOLDER**

CHEMIDEX PHARMA LIMITED  
8A CRABTREE ROAD  
EGHAM  
SURREY  
TW20 8RN  
UNITED KINGDOM

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 17736/0112

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

05/08/2008

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

27/03/2026