Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fleet Micro-enema Rectal Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml dose contains:

Sodium Citrate	450 mg
Sodium Lauryl Sulphoacetate	45 mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Rectal solution
Slight opaque solution with no particulate matter or turbidity.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of occasional constipation in bedridden patients and geriatrics.
Use in paediatrics and obstetrics should only be under medical supervision.

4.2 Posology and method of administration

Adults and children aged 3 years and older: Administer the contents of one Fleet Micro-enema rectally 15 minutes before effect is wanted.

Lie on left side with both knees bent, arms at rest.

Remove orange protective shield.

With steady pressure, gently insert enema full length into the rectum with tip pointing towards navel.

Squeeze tube until contents are expelled.

Discontinue use if resistance is encountered. Forcing an enema can result in injury.

4.3 Contraindications

It is advisable to avoid the use of Fleet Micro-enema in cases of haemorrhoid eruptions and in patients with inflammatory bowel diseases or any acute gastrointestinal conditions.

Do not use when there is a hypersensitivity to the active ingredients or any of the excipients.

Do not administer to children under 3 years of age.

4.4 Special warnings and precautions for use

Excessive use may cause diarrhoea and fluid loss which should be treated symptomatically.
Frequent or prolonged use of a laxative for more than one week may result in dependence.

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious problem.

In such cases Fleet Micro-enema should not be administered further and a doctor's advice sought.

This medicinal product contains propylene glycol which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

There is no data on toxicity in animals and man, therefore should only be used under medical supervision.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Not applicable.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Its laxative action is due to the combined action of Sodium Citrate, which acts by retaining fluid in the bowel by osmosis and by changing the pattern of water distribution in the faeces and Sodium Lauryl Sulphoacetate, a wetting agent.
Effective within 5-15 minutes.

5.2 Pharmacokinetic properties

The ingredients contained in Fleet Micro-enema are not absorbed or metabolised, but eliminated unchanged with the faeces.

5.3 Preclinical safety data

No specific remarkable findings.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sorbitol Liquid (non-crystallising)
Propylene Glycol
Carbomer
Nozzle lubricant: white soft paraffin

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

Fleet Micro-enema is available in a disposable 5ml tube. Finger guard, cap and protective sheath are made from LDPE while the soft pre-lubricated nozzle (Comfortip) is made from ethylene vinyl acetate.

The 5ml tubes are available in pack sizes of 1,4,6 and 12.

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

EC De Witt & Company Limited
Tudor Road
Manor Park
Runcorn
Cheshire
WA7 1SZ
England

8 MARKETING AUTHORISATION NUMBER

PA 299/14/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 November 1996

Date of last renewal: 06 July 2005

10 DATE OF REVISION OF THE TEXT

February 2006