Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Codalax Forte 1000mg/75mg per 5ml suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5ml of suspension contains 1000mg Poloxmer 188 and 75mg Dantron.

Excipients: Each 5ml also contain: 1000mg Sorbitol liquid (non-crystallising), 0.2ml 96% ethanol and 10mg Niasept sodium containing sodium ethyl, methyl and propyl parahydroxybenzoate (E 215, E 219 and E 217)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

Orange-yellow coloured oral suspension, with an odour of peach and a sweet taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Use only in the treatment of analgesic induced constipation in the terminally ill patient.

4.2 Posology and method of administration

Oral

Adults and Elderly
One 5 ml spoonfuls at bedtime.

Children
Not recommended for children under twelve years of age.

4.3 Contraindications

- In common with other gastro-intestinal evacuants, CODALAX and CODALAX Forte suspensions should not be given when acute or painful conditions of the abdomen are present or when the cause of constipation is suspected to be intestinal obstruction.
- Pregnancy.
- Hypersensitivity to any of the constituents of the products.

4.4 Special warnings and precautions for use

- Oral administration of dantron has been reported to cause intestinal tumours in rats and mice. It has also been reported to be hepatocarcinogenic in rats as well as in mice. There is no sound evidence to conclude a no effect dose and therefore there may be a risk of such effects in humans.

- In babies, children and patients wearing nappies, there may be staining of the buttocks. This may lead to superficial

sloughing of the skin. Therefore, CODALAX and CODALAX Forte suspensions should not be given to infants in nappies, and used with caution in all incontinent patients.

- Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

CODALAX and CODALAX Forte suspensions should not be administered during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Dantron may cause temporary harmless pink or red colouring of the urine and peri-anal skin. In prolonged high dosage, the mucosa of the large intestine may become coloured.

4.9 Overdose

In case of overdosage patients should be given plenty of fluids. An anticholinergic agent such as atropine sulphate may be given to offset excessive intestinal motility.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dantron, combinations
ATC code: A06 AB53

CODALAX Forte suspension owes its laxative action to the mild purgative dantron. This is an anthraquinone, derivative chemically related to emodin, the active principle of cascara and other naturally occurring products such as senna, aloes and rhubarb. It acts on the nerve endings of the myenteric plexus and stimulates the muscles of the large intestine.

Poloxamer 188 is a wetting agent which increases the penetration of water into faecal material. The surface activity of the poloxamer has a lubricant effect on the gut contents.

5.2 Pharmacokinetic properties

Like other anthraquinone compounds, dantron is partially absorbed from the small intestine, where it has no action, and is carried via the circulation to the large intestine where it acts on the nerve endings of the myenteric plexus to stimulate the muscles of the large intestine. Because it does not affect the small intestine, griping and cramping do not occur. Dantron begins to act between 6 and 12 hours after administration.

Poloxamer 188, a non-ionic surfactant is not absorbed and is fully recovered in the faeces.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other

sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Sorbitol liquid (non crystallising)
Ethanol 96%
Propylene Glycol
Magnesium aluminium silicate
Peach Flavour
Capsicum oleoresin
Glyceryl mono/di - oleate
Disodium phosphate dodecahydrate
Niasept sodium containing:
Sodium methylparahydroxybenzoate (E219)
Sodium ethylparahydroxybenzoate (E215)
Sodium propylparahydroxybenzoate (E217)
Citric Acid monohydrate
Potassium sorbate
Saccharin sodium
Potable Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in the original container.

6.5 Nature and contents of container

Ambler glass bottles with steran wadded metal closures or child-resistant, tamper-evident closures containing 30ml, 50 ml, 100 ml, 250 ml, 300 ml, 500 ml suspension.

Amber glass bottles with black plastic screw caps or child-resistant, tamper-evident closures containing 1 litre suspension.

Amber PET bottles with child-resistant, tamper-evident closures containing 30ml, 50ml, 100 ml, 250ml, 300ml or 1 litre suspension.

Not all pack sizes may be marketed.

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

Mundipharma Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER

PA 1688/3/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 March 1993

Date of last renewal: 26 March 2008

10 DATE OF REVISION OF THE TEXT

January 2011