# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

CODALAX FORTE 500mg/37.5mg capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 500 mg Poloxamer 188 and 37.5 mg Dantron.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, hard (capsule)
Opaque green/light brown, size 0, hard gelatin capsule marked ‘CXF’ and NAPP in white.

## 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

Recommended dosage:

Adults

One or two capsules at bedtime.

Children under 12 years

Not recommended.

Elderly

As recommended by the physician.

### 4.3 Contraindications

1. In common with other gastro-intestinal evacuants, CODALAX FORTE capsules should not be given when acute or painful conditions of the abdomen are present or when the cause of the constipation is thought to be intestinal obstruction.

2. Pregnancy and lactation.

3. Hypersensivity to any of the constituents of the product.

## 4.4 Special warnings and precautions for use

1. Oral administration of dantron has been reported to cause liver or intestinal tumours in rats and mice. There is no sound evidence to conclude a no effect dose and therefore there may be a risk of such effects in humans. CODALAX FORTE use should therefore be restricted to the licensed indications.

2. 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 FORTE should not be given to infants in nappies and should be used with caution in all incontinent patients.

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

None stated.

## 4.6 Fertility, pregnancy and lactation

CODALAX FORTE capsules are contraindicated in pregnant women and nursing mothers.

## 4.7 Effects on ability to drive and use machines

None stated.

## 4.8 Undesirable effects

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

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

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

## 4.9 Overdose

In cases of overdosage, patients should be given plenty of fluids. An anti-cholinergic preparation such as atropine sulphate may be given to offset the excessive intestinal motility.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

*Pharmacotherapeutic group: Dantron, combinations*
*ATC code: A06 AB53*

Dantron is an anthraquinone derivative, which 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. Because it does not affect the small intestine, griping and cramping do not occur. Dantron begins to act between 6 - 12 hours after administration. Poloxamer 188 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)

Capsule shell
Contains:
Gelatin
Erythrosine (E127)
Iron oxide (E172)
Indigo carmine (E132)
Titanium dioxide (E171)
Sodium laurilsuphfate

Printing ink
Opacode S-1-7085
Contains:
Shellac
Simeticone
Propylene glycol (E1520)
Titanium dioxide (E171)

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

Three years.

## 6.4 Special precautions for storage

Do not store above 30$^{o}$C.

## 6.5 Nature and contents of container

a) Polypropylene containers with polyethylene lids

b) PVdC coated PVC blister packs with aluminium backing foil.

Pack sizes of 30 and 60 capsules and medical sample packs of 4 and 10 capsules.

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
Millbank House
Arkle Road
Sandyford
Dublin 18
Ireland

## 8 MARKETING AUTHORISATION NUMBER

PA1688/003/002

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

Date of first authorisation: 26 June 1995

Date of last renewal: 26 March 2008

## 10 DATE OF REVISION OF THE TEXT

June 2015