SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Co-danthrusate 50/60mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 50 mg Dantron and 60 mg Docusate sodium

Excipient with known effect: Each capsule contains 95 mg of lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule

Brown size 2 capsules coded CDN in white on cap and body containing a yellow powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Constipation in terminally ill patients of all ages

4.2 Posology and method of administration

Posology

Adults and elderly
Co-danthrusate Capsules are given in doses of 1-3 capsules in adults including elderly patients.

Paediatric population
Children between the ages of 6 to 12 years are given 1 capsule.

Doses are usually given at bedtime.

Children under 6 years - not recommended.

Method of Administration: Oral

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Like all laxatives, Co-danthrusate is contraindicated in cases of intestinal obstruction or undiagnosed abdominal pain.

4.4 Special warnings and precautions for use

In experimental animals, Dantron has been associated with adenocarcinomas in the bowel and tumours in the liver. A theoretical risk of similar effects in humans cannot be excluded.

Dantron is excreted in the urine and metabolised dantron in the faeces. There is evidence that these may cause perineal erythema in patients with urinary and or faecal incontinence. It is recommended therefore that co-danthrusate should be used with caution in all incontinent patients.

Prolonged use is not recommended.

Dantron-containing laxatives like co-danthrusate should not be used for the general management of constipation in the elderly.

Co-danthrusate capsules contain lactose. Patients with rare hereditary problems of galactose intolerance, fructose intolerance, sucrose-isomaltase insufficiency, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Docusates may enhance the gastrointestinal or hepatic cell uptake of other drugs potentiating their activity and possibly increasing their toxicity. They should not be used with liquid paraffin.

4.6 Fertility, Pregnancy and lactation

Co-danthrusate should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

Occasionally an orange tint in the urine may be observed due to the dantron component.

A mild griping feeling in the abdomen may occur.

Skin rash may occur and reports of skin irritation, skin discolouration and superficial sloughing of the perianal skin have been reported after prolonged use of co-danthrusate.

Prolonged use or high doses of stimulant laxatives like co-danthrusate may lead to fluid and electrolyte imbalance, colonic atony, melanosis coli (discolouration of the colonic mucosa) and tolerance to their effects.

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 internet at www.mhra.gov.uk/yellowcard.

4.9 Overdose

After overdosage, the patient should be encouraged to drink plenty of fluids. An anticholinergic preparation may be necessary to ease excessive intestinal motility.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Contact Laxatives

ATC Code: A06AB

Dantron is an anthraquinone stimulant laxative which is given by mouth to treat constipation.

Docusates are faecal softeners. They are anionic surfactants which act by increasing the penetration of fluid into the faeces.

Co-danthrusate Capsules are poorly absorbed from the small intestine. Their effects are limited mainly to the large intestine and occur 6 hours or more after oral administration.

5.2 Pharmacokinetic properties

Dantron

Absorption

Dantron is absorbed from the small intestine to some extent.

Elimination

It is excreted in the bile, saliva, faeces and urine, also in secretions including breast milk.

Docusate

Absorption

Docusate salts are absorbed from the gastro-intestinal tract.

Elimination

It is excreted in bile.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose	BP
Pre-gelatinised Starch	BP
Colloidal Silicon Dioxide	BP
Magnesium Stearate	BP

Sodium Benzoate USNF/BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

White PVdC film (250µm/60gm^{-2}) aluminium (20µm) foil blister packs, and yellow PVC film (350µm) aluminium (30µm) blister packs. 21, 28, 42, 56 and 63 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Activase Pharmaceuticals Limited

11 Boumpoulinas

Nicosia

1060

Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 28444/0228

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/03/2009

10 DATE OF REVISION OF THE TEXT

19/09/2017