SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> <STRENGTH> Oral Solution

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of oral solution contains <STRENGTH> of docusate sodium

Excipient with known effect:

<REGARDING THE APPROVAL>

For the full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Oral Solution

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications
2. To prevent and treat chronic constipation
3. Asanadjunctinabdominalradiologicalprocedures.
   1. Posology and method of administration

Posology <REGARDING THE APPROVAL>

*Children:* 12.5mg <XX ml> to 25mg <XX ml> three times daily. Dilute the medicine in a glass of flavoured drink eg fruit juice or milk. Drink the diluted medicine within 30 minutes of preparation.

*Infants (Over six months):* 12.5mg <XX ml> three times daily. Dilute the medicine in a glass of flavoured drink eg fruit juice or milk. Drink the diluted medicine within 30 minutes of preparation.

*For barium meals:* 75mg <XX ml>

to be taken with meal.

*Adults:* 100mg <XX ml> to 150mg <XX ml> three times a day. Take as a single dose followed by plenty of water or flavoured drink e.g. milk or orange juice. Maximum daily dose 500mg. <XX ml>

Treatment should be commenced with large doses which should be decreased as the condition of the patient improves.

*For barium meals:* 400mg <XX ml> to be taken with the meal.

*Elderly:* There is no evidence to suggest that an adjustment of the dosage is necessary in the elderly.

Method of administration

Oral use.

* 1. Contraindications

Docusate sodium should not be taken:

* by patients with a known hypersensitivity to docusate sodium or to any of the excipients listed in section 6.1.
* in the presence of abdominal pain, intestinal obstruction, nausea or if vomiting occurs.
  1. Special warnings and precautions for use

Paediatric population

Docusate sodium oral solution should not be given to infants under six months. <REGARDING THE APPROVAL>

Prolonged use can precipitate the onset of an atonic non-functioning colon and hypokalaemia.

Docusate sodium contains sorbitol. This medicine contains 1290 mg sorbitol in each 5 mL dose. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. <REGARDING THE APPROVAL>

Docusate sodium contains methyl p-hydroxybenzoate and propyl p-hydroxybenzoate. This medicine contains 5 mg of methyl p- hydroxybenzoate and 2.5 mg of propyl p-hydroxybenzoate in each dose (5 mL). May cause allergic reactions (possibly delayed). <REGARDING THE APPROVAL>

Docusate sodium contains aspartame. This medicine contains 15 mg aspartame in each dose (5 mL). Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the bosy cannot remove it properly. <REGARDING THE APPROVAL>

Docusate sodium contains sodium benzoate. This medicine contains 5 mg sodium benzoate in each dose (5 mL). <REGARDING THE APPROVAL>

Docusate sodium contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per 5 mL dose, that is to say essentially ‘sodium-free’.

* 1. Interaction with other medicinal products and other forms of interaction

Docusate sodium should not be taken concurrently with mineral oil. Anthraquinone derivatives should be taken in reduced doses, if administered with Docusate Sodium Adult as their absorption is increased.

* 1. Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of safety of the drug in human pregnancy, nor is there evidence from animal work that it is free from hazard, but it has been in wide use for many years without apparent ill consequence. Use in pregnancy only if the benefits outweigh the potential risks.

Breastfeeding

Docusate sodium is excreted in breast milk and should therefore be used with caution in lactating mothers.

* 1. Effects on ability to drive and use machines

None known.

* 1. Undesirable effects

Frequencies are defined as follows: Very common (≥1/10); common (≥1/100 to ≤ 1/10); uncommon (≥1/1,000 to ≤ 1/100); rare (≥1/10,000 to ≤ 1/1,00); very rare (≤ 1/10,000), not known (cannot be estimated from the available data).

*Gastrointestinal disorders:*

Rare: diarrhoea, nausea, abdominal cramps.

*Skin and subcutaneous tissue disorders:*

Not known: skin rash and pruritus.

There have been spontaneous reports of burning sensation in mouth and throat following the use of docusate sodium. Patients are advised to drink plenty of water or flavoured drink after taking the solution.

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 Health Product Vigilance Center; HPVC

* 1. Overdose

In rare cases of overdose excessive loss of water and electrolytes should be treated by encouraging the patient to drink plenty of fluid.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: Laxatives, softeners, emollients, ATC code: A06AA02

Docusate sodium acts as a faecal softener by increasing the penetration of water and fats.

* 1. Pharmacokinetic properties

Docusate sodium exerts its effects by means of its physical surfactant properties. However there is some evidence that it is absorbed from the gastrointestinal tract and excreted in bile.

* 1. Preclinical safety data

Not stated.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

None known.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>