SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Docusol Paediatric
Docusate Sodium Paediatric 12.5mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5ml of the solution contains docusate sodium 12.5mg

Excipient(s) with known effect:

Aspartame (E951) 15 mg per dose of syrup (5 mL)

Sorbitol 70% (E420) 903 mg per dose of syrup (5 mL)

Glycerol (E422) 628.5 mg per dose of syrup (5 mL)

Methyl p-hydroxybenzoate (E218) 50 mg per dose of syrup (5 mL)

Propyl p-hydroxybenzoate (E216) 25 mg per dose of syrup (5 mL)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

a) To prevent and treat chronic constipation
b) As an adjunct in abdominal radiological procedures

4.2 Posology and method of administration

For oral administration

Children: one to two 5ml spoonfuls 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): one 5ml spoonful 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.

Adults: not appropriate for adults or elderly. For administration to adults use Docusol Adult Solution.

For barium meals: 30ml to be taken with meal.

4.3 Contraindications

Docusol solution 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.

4.4 Special warnings and precautions for use

Docusol should not be given to infants under six months. Prolonged use can precipitate the onset of an atonic non-functioning colon and hypokalaemia.

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

Docusol solution should not be taken concurrently with mineral oil.

Anthraquinone derivatives should be taken in reduced doses, if administered with Docusol as their absorption is increased.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Stimulant laxatives increase intestinal motility and often cause abdominal cramp.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reaction 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 Yellow Card Scheme

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

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: A06AA02 Laxatives, softeners, emollients.

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

5.2 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.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Strawberry flavour

Aspartame

Sorbitol 70%

Glycerol

Povidone

Methyl p-hydroxybenzoate

Propyl p-hydroxybenzoate

Sodium acid phosphate

Sodium phosphate

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

None

6.5 Nature and contents of container

Glass bottle with a plastic screw cap. Each bottle contains 100ml, 125ml or 300ml.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Typharm Ltd.
Unit 14D
Wendover Road
Rackheath Industrial Estate
Norwich
NR13 6LH

8 MARKETING AUTHORISATION NUMBER(S)

PL 00551/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/03/1998 / 13/07/2006

10 DATE OF REVISION OF THE TEXT

23/12/2015