SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Docusol Adult
Docusate Sodium Adult 50mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5ml of the solution contains docusate sodium 50mg

Excipient(s) with known effect:
Aspartame (E951) 15 mg per dose of syrup (5 mL)
Sorbitol 70% (E420) 1209 mg per dose of syrup (5 mL)
Glycerol (E422) 628.5 mg per dose of syrup (5 mL)
Methyl p-hydroxybenzoate (E218) 5 mg per dose of syrup (5 mL)
Propyl p-hydroxybenzoate (E216) 2,5 mg per dose of syrup (5 mL)
Propylene Glycol (E1520) 0,003 mL per dose of syrup (5 mL)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution
Liquid syrupy, clear, nearly colorless and with homogeneous appearance.

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

Adults: 10ml to 15ml 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 50ml.

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

For barium meals: 40ml to be taken with the meal.

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

Children: For administration to children and infants over 6 months use Docusol Paediatric Solution 0.25% w/v.

For barium meals: 40ml to be taken with the 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.

Docusol Adult Solution contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Docusol Adult Solution contains glycerol. May cause headache, stomach upset and diarrhoea.

Docusol Adult Solution contains methyl p-hydroxybenzoate and propyl p-hydroxybenzoate. May cause allergic reactions (possibly delayed).

Docusol Adult Solution contains aspartame which is a source of phenylalanine. May be harmful for people with phenylketonuria.

Docusol Adult Solution contains propylene glycol which may cause alcohol-like symptoms.

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

Sorbitol 70%
Glycerol
Povidone
Methyl p-hydroxybenzoate

Propyl p-hydroxybenzoate
Sodium dihydrogen phosphate dihydrate
Disodium hydrogen phosphate dodecahydrate
Sodium benzoate
Citric acid anhydrous
Aspartame
Strawberry flavour
Propylene glycol
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 with a transparent seal. Each bottle contains 125ml or 300ml.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Typharm Ltd.
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8 MARKETING AUTHORISATION NUMBER(S)

PL 00551/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/03/1998 / 13/07/2006

10 DATE OF REVISION OF THE TEXT

03/05/2016