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 50 mg docusate sodium

Excipient(s) with known effect:
Aspartame (E 951) 15 mg per dose of syrup (5 mL)
Sorbitol 70% (E 420) 1290 mg per dose of syrup (5 mL)
Methyl p-hydroxybenzoate (E 218) 5 mg per dose of syrup (5 mL)
Propyl p-hydroxybenzoate (E 216) 2.5 mg per dose of syrup (5 mL)
Sodium benzoate (E 211) 5 mg per dose of syrup (5 mL)
Sodium 12.6 mg 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

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

4.3 Contraindications

Docusate Sodium Adult 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

Paediatric population

Docusate Sodium Adult is not recommended for children aged 12 years and under.

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

Docusate Sodium Adult Solution 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.

Docusate Sodium Adult Solution 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).

Docusate Sodium Adult Solution 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.

Docusate Sodium Adult Solution contains sodium benzoate. This medicine contains 5 mg sodium benzoate in each dose (5 mL).

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

4.5 Interaction with other medicinal products and other forms of interaction

Docusate Sodium Adult Solution 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.

4.6 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.

4.7 Effects on ability to drive and use machines

None known

4.8 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 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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% (E 420)
Glycerol (E 422)
Povidone
Methyl p-hydroxybenzoate (E 218)
Propyl p-hydroxybenzoate (E 216)
Sodium dihydrogen phosphate dehydrate
Disodium hydrogen phosphate dodecahydrate
Sodium benzoate (E 211)
Citric acid anhydrous
Aspartame (E 951)
Strawberry flavour
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

This product does not require any special storage conditions.

6.5 Nature and contents of container

Glass bottle with a plastic screw cap with a transparent seal. Each bottle contains 125ml or 300ml.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Typharm Ltd.
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39 Mahoney Green
Rackheath
Norwich
NR13 6JY

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

19/01/2024