SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5 ml of the solution contains 12.5 mg docusate sodium.

Excipient(s) with known effect:

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

Sorbitol 70% (E420) 1290 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)

Sodium < 23 mg per dose of syrup (5 mL)

For 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

Posology

Children: one to two 5ml spoonfuls three times daily. Dilute the medicine in a glass of flavoured drink e.g. 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 e.g. 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.

Method of administration

Oral use.

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

Docusol Paediatric contains sorbitol.
This medicine contains 1290 mg sorbitol in each dose (5 mL). Sorbitol is a source of fructose. If the patient has an intolerance to some sugars or has herediatary fructose intolerance (HFI), a rare genetic disorder, the patient must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Docusol Paediatric contains 5 mg methyl p-hydroxybenzoate and 2.5 mg propyl p-hydroxybenzoate in each 5 mL dose.

May cause allergic reactions (possibly delayed).

Docusol Paediatric contains aspartame.
This medicine contains 15 mg of aspartame per dose (5 mL). Aspartame is a source of phenylalanine. It may be harmful to patients with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Docusol Paediatric 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

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

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

6.1 List of excipients

Strawberry flavour
Aspartame (E951)
Sorbitol (70%) (E420)
Glycerol (E422)
Povidone
Methyl p-hydroxybenzoate (E218)
Propyl p-hydroxybenzoate (E216)
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.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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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

22/01/2024