SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Docusate Sodium Paediatric 12.5mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5ml of the solution contains 12.5mg 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 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

Posology

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 Typharm Docusate Sodium Paediatric Adult Solution.

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

Method of administration

Oral use.

4.3 Contraindications

Docusate Sodium Paediatric should not be taken:

- by patients with a known hypersensitivity to the active substance 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

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

Docusate Sodium Paediatric contains sorbitol.

This medicine contains 1290 mg sorbitol in each dose (5 mL). Sorbitol is a source of fructose so should not be given to patients who have an intolerance to some sugars or have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Docusate Sodium Paediatric 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).

Typharm Docusate Sodium Paediatric contains aspartame.

This medicine contains 15 mg of aspartame per 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 body cannot remove it properly.

Docusate Sodium 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

Docusate Sodium Paediatric should not be taken concurrently with mineral oil. Anthraquinone derivatives should be taken in reduced doses, if administered with Typharm Docusate Sodium Paediatric 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

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

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 flavor

Aspartame (E951)

Sorbitol 70% (E420)

Glycerol (E422)

Povidone

Methyl p-hydroxybenzoate (E218)

Propyl p-hydroxybenzoate (E216)

Monosodium Phosphate dihydrate

Disodium phosphate dodecahydrate

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

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

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8 MARKETING AUTHORISATION NUMBER(S)

PL 00551/0237

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/04/2025

10 DATE OF REVISION OF THE TEXT

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