

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Docusol Constipation Relief 50 mg/5 ml Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5ml of the solution contains 50mg docusate sodium

Excipient(s) with known effect:

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

Sodium benzoate (E 211) 5 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.

Liquid syrupy, clear, nearly colourless and with homogeneous appearance.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of chronic constipation. Prevention of hard dry stools and reduction of straining at stools in the presence of conditions like haemorrhoids and anal fissures.

4.2 Posology and method of administration

Posology

Adults: 10 mL 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 30 mL.

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

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

Paediatric population

Children aged 6 months to 12 years: use Docusol Paediatric 12.5 mg/5 ml Solution.

Duration of treatment

The patient should be advised to consult a physician when constipation persists or worsens during treatment or when laxatives are needed for a long period of time.

Method of administration

Oral use.

4.3 Contraindications

Docusol Constipation Relief 50 mg/5 ml Solution 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

Paediatric population

Docusol Constipation Relief 50 mg/5 ml Solution is not recommended for children aged 12 years and under.

Docusol Constipation Relief 50 mg/5 ml Solution contains sorbitol.

This medicine contains 1290 mg sorbitol in each 5 mL dose. 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.

Docusol Constipation Relief 50 mg/5 ml Solution contains 5 mg of methyl p-hydroxybenzoate in each 5 mL dose and 2.5 mg of propyl p-hydroxybenzoate in each 5 mL dose. May cause allergic reactions (possibly delayed).

Docusol Constipation Relief 50 mg/5 ml 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 body cannot remove it properly.

Docusol Constipation Relief 50 mg/5 ml Solution contains sodium benzoate. This medicine contains 5 mg sodium benzoate in each dose (5 mL).

Docusol Constipation Relief 50 mg/5 ml Solution 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 Constipation Relief 50 mg/5 ml Solution should not be taken concurrently with mineral oil. Anthraquinone derivatives should be taken in reduced doses, if administered with Docusol Constipation Relief 50 mg/5 ml Solution 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 ($\geq 1/10$); common ($\geq 1/100$ to $\leq 1/10$); uncommon ($\geq 1/1,000$ to $\leq 1/100$); rare ($\geq 1/10,000$ to $\leq 1/1,000$); very rare ($\leq 1/10,000$), 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

Sorbitol 70% (E420)

Glycerol (E422)
Povidone
Methyl p-hydroxybenzoate (E218)
Propyl p-hydroxybenzoate (E216)
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dodecahydrate
Sodium benzoate
Citric acid anhydrous
Aspartame (E591)
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

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8 MARKETING AUTHORISATION NUMBER(S)

PL 00551/0236

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

15/04/2025

10 DATE OF REVISION OF THE TEXT

15/04/2025