



Read all of this leaflet carefully before the patient starts using this medicine because it contains important information for you. This medicine is available without prescription.

Always use this medicine exactly as described in this leaflet or as the patient's doctor or pharmacist have told you.

- **Keep this leaflet. You may need to read it again.**
- **Ask the patient's pharmacist if you need more information or advice.**
- **If the patient get any side effects, talk to the patient's doctor or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4.**
- **You must talk to a doctor if the patient does not feel better or if the patient feels worse after a few days.**

What is in this leaflet:

1. What Docusol Paediatric Solution is and what it is used for
2. What you need to know before the patient takes Docusol Paediatric Solution
3. How to take Docusol Paediatric Solution
4. Possible side effects
5. How to store Docusol Paediatric Solution
6. Contents of the pack and other information

1. WHAT DOCUSOL PAEDIATRIC SOLUTION IS AND WHAT IT IS USED FOR

Docusol Paediatric Solution is one of a group of medicines called 'laxatives'. They are usually used to prevent and treat constipation. Docusol Paediatric Solution may also be used before a stomach X ray.

2. WHAT YOU NEED TO KNOW BEFORE THE PATIENT TAKES DOCUSOL PAEDIATRIC SOLUTION

Do not give Docusol Paediatric Solution

- if the patient is allergic to docusate sodium or any of the other ingredients of this medicine (listed in section 6).
- if the patient is suffering from stomach pains or an obstruction in the gut.
- if the patient is feeling sick or has been sick in the last 24 hours.

Warnings and precautions

Talk to the patient's doctor or pharmacist before the patient starts taking Docusol Paediatric Solution.

- Docusol Paediatric Solution should not be given to infants under the age of 6 months.
- Prolonged use can cause the gut to become lazy and not work properly.

Other medicine and Docusol Paediatric Solution

Tell the patient's doctor or pharmacist if the patient is taking, have recently taken or might take any other medicines.

Docusol Paediatric Solution should not be taken if the patient is already taking mineral oil. Patients already taking other laxatives called anthraquinone laxatives such as senna, will need to take reduced doses as Docusol Paediatric Solution increases their effects.

Taking Docusol Paediatric Solution with food and drink

Docusol Paediatric Solution can be taken with food and drink.

Important information about some of the ingredients of Docusol Paediatric Solution

Docusol Paediatric 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 (5ml). May cause allergic reactions (possibly delayed).

Docusol Paediatric Solution contains sorbitol.

This medicine contains 1290 mg of sorbitol in each dose (5 ml). Sorbitol is a source of fructose. If the patient's doctor has told you that the patient has an intolerance to some sugars or if the patient has been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to a doctor before the patient takes this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Docusol Paediatric Solution 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.

Docusol Paediatric Solution contains sodium

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

3. HOW TO TAKE DOCUSOL PAEDIATRIC SOLUTION

Always take this medicine exactly as described in this leaflet or as the patient's doctor or pharmacist have told you. Check with the patient's doctor or pharmacist if you are not sure.

Constipation:

The recommended dose for infants aged over 6 months is one 5ml spoonful three times a day.

The recommended dose for children aged 2-12 years is one to two 5ml spoonfuls three times a day.

Dilute the medicine in a glass of flavoured drink such as fruit juice or milk and give to the patient to drink within 30 minutes of preparation.

This medicine should not be given to infants under the age of 6 months.

Reduce the dose as the condition improves.

Use before stomach X-ray:

When taken before a stomach X-ray the dose is six 5ml spoonfuls, as a single dose.

Docusate sodium may cause an unpleasant aftertaste or burning sensation.

This may be minimised by drinking plenty after taking the solution.

If the patient takes more Docusol Paediatric Solution than they should

If the patient takes more Docusol Paediatric Solution than they should, the patient should drink lots of water. The nearest hospital casualty department should be contacted or the patient's doctor must be informed immediately.

If the patient forgets to take Docusol Paediatric Solution

Give the patient their usual dose and then continue the normal course of treatment. Do not give a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask the doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, stop taking Docusol Paediatric Solution and tell your doctor as soon as possible:

Rare: may affect up to 1 in 1,000 people

- Diarrhoea
- Feel sick
- Stomach cramps

Not known: frequency cannot be estimated from the available data

- Skin rash
- Pruritus (itching)

If the patient needs to take a laxative every day, or if the patient has a persistent stomach ache, they must see their doctor.

Docusate sodium may cause an unpleasant aftertaste or burning sensation.

This may be minimised by drinking plenty of water after taking the solution.

If any of the side effects gets serious, or if the patient notices any side effects not listed in this leaflet, please tell the patient's doctor or pharmacist.

Reporting of side effects

If the patient gets any side effects, talk to the patient's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOCUSOL PAEDIATRIC SOLUTION

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use Docusol Paediatric Solution after the expiry date that is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Docusol Paediatric Solution contains

- The active substance is docusate sodium (12.5mg/5ml)
- The other ingredients are sorbitol (E420), glycerol (E422), povidone, monosodium phosphate dihydrate, disodium phosphate dodecahydrate, methyl p-hydroxybenzoate (E218), propyl p-hydroxybenzoate (E216), strawberry flavour, aspartame (E951) and purified water.

What Docusol Paediatric Solution looks like and contents of the pack

Docusol Paediatric Solution is a clear liquid available in amber glass bottles of 125ml and 300ml with a plastic screw cap.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Typharm Ltd, Unit 1, 39 Mahoney Green, Rackheath, Norwich, NR13 6JY.

Manufacturer

Laboratórios Basi – Industria Farmacéutica, S.A., Parque Industrial Manuel Lourenco Ferreira, Lotes 8, 15 e 16 3450-232 Mortágua, Portugal

This leaflet was last revised in October 2023