

PACKAGE LEAFLET – INFORMATION FOR THE PATIENT
Docusate sodium 12.5mg/5ml oral solution
 Docusate sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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 you get any side effects, talk to the patient's doctor or pharmacist.
- This includes any possible side effects not listed in this 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 Docusate sodium oral solution is and what it is used for
2. What you need to know before the patient takes Docusate sodium oral solution
3. How to take Docusate sodium oral solution
4. Possible side effects
5. How to store Docusate sodium oral solution
6. Contents of the pack and other information

1. What Docusate oral solution is and what it is used for

Docusate sodium 12.5mg/5ml oral solution is one of a group of medicines called 'laxatives'. They are usually used to prevent and treat constipation. They may also be used before a stomach X-ray.

2. What you need to know before the patient takes Docusate sodium Oral Solution

Do not give Docusate sodium oral 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 Docusate sodium oral solution

- Docusate sodium oral 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 medicines and Docusate sodium oral solution

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

Docusate sodium oral solution should not be taken if you are already taking mineral oil. Patients already taking other laxatives called anthraquinone laxative such as senna, will need to take reduced doses as Docusate sodium oral solution increases their effects.

Taking Docusate sodium oral solution with food and drink

Docusate sodium oral solution can be taken with food and drink.

Pregnancy and breast-feeding

Do not use Docusate sodium oral solution if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Important information about some of the ingredients of Docusate sodium oral solution

Docusate sodium oral solution contains methyl parahydroxybenzoate and propyl parahydroxybenzoate.

This medicine contains 5mg of methyl p-hydroxybenzoate and 2.5 mg of propyl p-hydroxybenzoate in each dose (5ml). May cause allergic reactions (possibly delayed).

Docusate sodium oral solution contains sorbitol.

This medicine contains 840mg of sorbitol in each dose (5ml). 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.

Sodium content.

This medicinal product contains 29.7mg sodium (main component of cooking/table salt) per 30ml (maximum daily dose). This is equivalent to 1.5% of the recommended maximum daily intake of sodium for an adult.

3. How to take Docusate sodium oral 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 5ml three times a day.

The recommended dose for children aged 2-12 years is 5ml to 10 ml 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 30ml, 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 Docusate sodium oral solution than you should

If the patient takes more Docusate sodium oral 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 Docusate sodium oral solution

Give the patient their usual dose and then continue the normal course of treatment. Do not take 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 Docusate sodium 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 you get any side effects, talk to your 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 Docusate sodium Oral Solution

This medicinal product does not require any special storage condition. Keep this medicine out of the sight and reach of children. Do not use this medicine 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. Do not throw away any 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 Docusate sodium Oral Solution contains

- The active substance is docusate sodium (12.5mg/5ml)
- The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium dihydrogen phosphate dihydrate (E339i), disodium hydrogen phosphate dihydrate (E339ii), glycerol (E422), kollidon 90F (E1201), sorbitol 70% (E420), sucralose (E955), citric acid (E330), strawberry flavor and purified water

What Docusate sodium Oral Solution looks like and contents of the pack

Docusate sodium oral solution is a clear, colorless to pale yellow, viscous solution with strawberry odor available in an amber glass bottle of 300ml with a plastic screw cap. It comes with a dosing cup with 2.5 / 5 / 10 / 15 ml graduations.

Marketing Authorisation Holder

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 Direction

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