

LUCIS Docusate sodium 50mg/5ml & 100mg/5ml oral solution

Version 1 Created 29.09.20

Font: VAG Rounded Light & Bold 8.3pt (leading auto and as shown)

Now Version - 8 created 06.12.22

Profile size shown is 190 x 420mm (suggested profile 23.09.20)



FRONT

190 mm

PACKAGE LEAFLET – INFORMATION FOR THE PATIENT Docusate sodium 50mg/5ml oral solution Docusate sodium 100mg/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 your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist.
- This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel 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 you take 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 sodium oral solution is and what it is used for

Docusate sodium 50mg/5ml and 100mg/5ml oral solutions belong to 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 you take Docusate sodium oral solution

Do not take Docusate sodium oral solution

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Docusate sodium oral solution

- This medicine is not suitable for children aged 6 months to 12 years but a suitable alternative, Docusate sodium 12.5mg/5ml oral solution is available.
- Prolonged use can cause the gut to become lazy and not work properly.
- If you need to take a laxative everyday.
- If you have regular or constant stomach pain.

Other health conditions should be excluded before taking this medicine. The treatment of constipation with Docusate sodium is only additional to a healthy lifestyle and diet (such as increased intake of fluids, dietary fibre and exercise).

Other medicines and Docusate sodium oral solution

Tell your doctor or pharmacist if you are 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. If you are taking an anthraquinone laxative such as senna, you will need to reduce the dose 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 5ml oral solution. May cause allergic reactions (possibly delayed).

Docusate sodium oral solution contains sorbitol.

This medicine contains 840mg of sorbitol in 5ml oral solution. 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.

Docusate sodium oral solution contains sodium benzoate.

This medicine contains 5 mg sodium benzoate in 5ml oral solution.

Sodium content.

Docusate sodium 50mg/5ml oral solution contains 57.5 mg sodium (main component of cooking/table salt) per 50 ml dose (maximum daily dose). This is equivalent to 2.9% of the recommended maximum daily dietary intake of sodium for an adult.

Docusate sodium 100mg/5ml oral solution contains 28.8mg sodium (main component of cooking/table salt) per 25 ml dose (maximum daily dose). This is equivalent to 1.4% of the recommended maximum daily dietary 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 your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you are taking Docusate sodium 50mg/5ml oral solution

Constipation:

The recommended dose is 10-15ml three times a day. Take as a single dose followed by plenty of water or flavoured drink e.g. milk or orange juice. The maximum daily dose is 50ml. Reduce the dose as the condition improves.

Use before stomach X-ray:

When taken before a stomach X-ray, the dose is 40ml, as a single dose. Docusate sodium may cause an unpleasant aftertaste or burning sensation. This may be minimised by drinking plenty of water after taking the solution.

If you are taking Docusate sodium 100mg/5ml oral solution

Constipation:

The recommended dose is 5-7.5ml three times a day. Take as a single dose followed by plenty of water or flavoured drink e.g. milk or orange juice. The maximum daily dose is 25ml. Reduce the dose as the condition improves.

Use before stomach X-ray:

When taken before a stomach X-ray, the dose is 20ml, as a single dose. Docusate sodium may cause an unpleasant aftertaste or burning sensation. This may be minimised by drinking plenty of water after taking the solution.

If you take more Docusate sodium Oral Solution than you should

If you accidentally take more Docusate sodium oral solution than you should, drink lots of water and contact your nearest hospital casualty department, or tell your doctor immediately.

If you forget to take Docusate sodium oral solution

As soon as you remember, take a 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 you need to take a laxative every day, or if you have a persistent stomach ache, see your 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 you notice any side effects not listed in this leaflet, please tell your 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

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
- The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium benzoate (E211), 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 50mg/5ml 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.

Docusate sodium 100mg/5ml oral solution is a clear, colorless to pale yellow, viscous solution with strawberry odor available in an amber glass bottle of 150ml or 300ml with a plastic screw cap. It comes with a dosing cup with 2.5 / 5 / 10 / 15 ml graduations.

Marketing Authorisation Holder

Lucis Pharma Ltd
14 Aston Magna, Moreton in Marsh
Gloucestershire GL56 9QQ
United Kingdom

Manufacturer

LABOMED PHARMACEUTICAL COMPANY S.A.
84 Ioannou Metaxa str.,
19441, Koropi, Athens,
Greece

This leaflet was last revised in December 2022.

Product number

Laetus Pharmacod e

Laetus Pharmacod e
Direction