


<b>Title:</b>	Docusate Sodium PIL	<b>Colours (Non printed)</b> 
<b>Ref:</b>	DS/TY/A/50	
<b>Date:</b>	28/10/15	
<b>Size (mm):</b>	200x280mm	
<b>Modified:</b>	07/11/23	

## Package leaflet: Information for the patient

# Docusate Sodium Adult 50mg/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 Adult 50mg/5ml Oral Solution is and what it is used for
2. What you need to know before you take Docusate Sodium Adult 50mg/5ml Oral Solution
3. How to take Docusate Sodium Adult 50mg/5ml Oral Solution
4. Possible side effects
5. How to store Docusate Sodium Adult 50mg/5ml Oral Solution
6. Contents of the pack and other information

### 1. WHAT DOCUSATE SODIUM ADULT 50MG/5ML ORAL SOLUTION IS AND WHAT IT IS USED FOR

Docusate Sodium Adult 50mg/5ml Oral Solution is one of a group of medicines called 'laxatives'. They are usually used to prevent and treat constipation. Docusate Sodium Adult 50mg/5ml Oral Solution may also be used before a stomach X-ray.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOCUSATE SODIUM ADULT 50MG/5ML ORAL SOLUTION

#### Do not take Docusate Sodium Adult 50mg/5ml 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 Adult 50mg/5ml 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.

#### Other medicines and Docusate Sodium Adult 50mg/5ml Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Docusate Sodium Adult 50mg/5ml 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 Adult 50mg/5ml Oral Solution increases their effects.

#### Taking Docusate Sodium Adult 50mg/5ml Oral Solution with food and drink

Docusate Sodium Adult 50mg/5ml Oral Solution can be taken with food and drink.

#### Pregnancy and breast-feeding

Do not use Docusate Sodium Adult 50mg/5ml 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 Adult 50mg/5ml Oral Solution

**Docusate Sodium Adult 50mg/5ml Oral 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 (5 ml). May cause allergic reactions (possibly delayed).

#### Docusate Sodium Adult 50mg/5ml Oral Solution contains sorbitol.

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

#### Docusate Sodium Adult 50mg/5ml Oral 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.

#### Docusate Sodium Adult contains sodium benzoate

This medicine contains 5 mg sodium benzoate in each dose (5 ml).

#### Docusate Sodium Adult 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 DOCUSATE SODIUM ADULT 50MG/5ML 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.

#### Constipation:

The recommended dose is two to three 5ml spoonfuls 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 ten 5ml spoonfuls (50ml). Reduce the dose as the condition improves.

#### Use before stomach X-ray:

When taken before a stomach X-ray, the dose is eight 5ml spoonfuls, 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 Adult 50mg/5ml Oral Solution than you should

If you accidentally take more Docusate Sodium Adult 50mg/5ml 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 Adult 50mg/5ml 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 Adult 50mg/5ml Oral 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 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](http://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 ADULT 50MG/5ML 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 Adult 50mg/5ml Oral Solution contains

- The active substance is docusate sodium (50mg/5ml)
- The other ingredients are sorbitol (E420), glycerol (E422), povidone, methyl p-hydroxybenzoate (E218), propyl p-hydroxybenzoate (E216), sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium benzoate (E212), citric acid anhydrous (E330), aspartame (E951), strawberry flavour and purified water.

#### What Docusate Sodium Adult 50mg/5ml Oral Solution looks like and contents of the pack

Docusate Sodium Adult 50mg/5ml Oral Solution is a clear liquid available in an amber glass bottle of 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 – Indústria Farmacêutica, S.A., Parque Industrial Manuel Lourenco Ferreira, Lotes 8, 15 e 16 3450-232 Mortágua, Portugal

This leaflet was last revised in October 2023