

**Package Leaflet**

## PACKAGE LEAFLET – INFORMATION FOR THE PATIENT

### **Docosate sodium 50mg/5ml oral solution**

### **Docosate sodium 100mg/5ml oral solution**

Docosate 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 Docosate sodium oral solution is and what it is used for
2. What you need to know before you take Docosate sodium oral solution
3. How to take Docosate sodium oral solution
4. Possible side effects
5. How to store Docosate sodium oral solution
6. Contents of the pack and other information

#### **1. What Docosate sodium oral solution is and what it is used for**

Docosate 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 Docosate sodium oral solution**

##### **Do not take Docosate sodium oral solution**

- if you are allergic to docosate 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 Docosate sodium oral solution

- This medicine is not suitable for children aged 6 months to 12 years but a suitable alternative, Docosate 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](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 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 Holders:**

**Docusate sodium 50mg/5ml oral solution**

Rosemont Pharmaceuticals Ltd  
Yorkdale Industrial Park, Braithwaite Street  
Leeds, LS11 9XE  
United Kingdom

**Docusate sodium 100mg/5ml oral solution**

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United Kingdom

**Manufacturer**

LABOMED PHARMACEUTICAL COMPANY S.A.  
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