

# Package leaflet: Information for the patient

## Docosate Sodium Paediatric 12.5mg/5ml Oral Solution

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 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 Docosate Sodium Paediatric 12.5mg/5ml Oral Solution is and what it is used for
2. What you need to know before the patient takes Docosate Sodium Paediatric 12.5mg/5ml Oral Solution
3. How to take Docosate Sodium Paediatric 12.5mg/5ml Oral Solution
4. Possible side effects
5. How to store Docosate Sodium Paediatric 12.5mg/5ml Oral Solution
6. Contents of the pack and other information

### 1. WHAT DOCUSATE SODIUM PAEDIATRIC 12.5MG/5ML ORAL SOLUTION IS AND WHAT IT IS USED FOR

Docosate Sodium Paediatric 12.5mg/5ml Oral Solution is one of a group of medicines called 'laxatives'. They are usually used to prevent and treat constipation. Docosate Sodium Paediatric 12.5mg/5ml Oral Solution may also be used before a stomach X-ray.

### 2. WHAT YOU NEED TO KNOW BEFORE THE PATIENT TAKES DOCUSATE SODIUM PAEDIATRIC 12.5MG/5ML ORAL SOLUTION

**Do not give Docosate Sodium Paediatric 12.5mg/5ml Oral Solution**

- if the patient is allergic to Docosate 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.

**Take special care with Docosate Sodium Paediatric 12.5mg/5ml Oral Solution**

- Docosate Sodium Paediatric 12.5mg/5ml 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 Docosate Sodium Paediatric 12.5mg/5ml Oral Solution**

Tell the patient's doctor or pharmacist if the patient is taking, have recently taken or might take any other medicines. Docosate Sodium Paediatric 12.5mg/5ml Oral 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 Docosate Sodium Paediatric 12.5mg/5ml Oral Solution increases their effects.

**Taking Docosate Sodium Paediatric 12.5mg/5ml Oral Solution with food and drink**

Docosate Sodium Paediatric 12.5mg/5ml Oral Solution can be taken with food and drink.

**Pregnancy and breast-feeding**

Do not use Docosate Sodium Paediatric 12.5mg/5ml Oral Solution if the patient is pregnant or breast-feeding, think the patient may be pregnant or are planning to have a baby, ask the patient's doctor or pharmacist for advice before taking this medicine.

**Important information about some of the ingredients of Docosate Sodium Paediatric 12.5mg/5ml Oral Solution**

Docosate Sodium Paediatric 12.5mg/5ml Oral Solution contains methyl p-hydroxybenzoate and propyl p-hydroxybenzoate which may cause allergic reactions, possibly delayed.

Docosate Sodium Paediatric 12.5mg/5ml Oral Solution contains glycerol. It may cause headache, stomach upset and diarrhoea.

Docosate Sodium Paediatric 12.5mg/5ml Oral Solution contains sorbitol. Each 5ml dose contains 0.9g of sorbitol. If the patient has been told by their doctor that they have an intolerance to sorbitol, contact their doctor before they take this medicine.

Docosate Sodium Paediatric 12.5mg/5ml Oral Solution contains aspartame which is a source of phenylalanine. May be harmful for people with phenylketonuria.

### 3. HOW TO TAKE DOCUSATE SODIUM PAEDIATRIC 12.5MG/5ML 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 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 your child/infant 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.

Docosate sodium may cause an unpleasant aftertaste or burning sensation. This may be minimised by drinking plenty of water after taking the solution.

**If the patient takes more Docosate Sodium Paediatric 12.5mg/5ml Oral Solution than they should**

If the patient takes more Docosate Sodium Paediatric 12.5mg/5ml 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 Docosate Sodium Paediatric 12.5mg/5ml Oral 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. Laxatives can increase movement of the intestines and often cause abdominal cramps.

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

Docosate 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](http://www.mhra.gov.uk/yellowcard)**

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

### 5. HOW TO STORE DOCUSATE SODIUM PAEDIATRIC 12.5MG/5ML ORAL SOLUTION

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw 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 Docosate Sodium Paediatric 12.5mg/5ml Oral Solution contains**

- The active substance is Docosate sodium, (12.5mg/5ml)
- The other ingredients are sorbitol (E420), glycerol (E422), povidone, sodium acid phosphate (E339), sodium phosphate (E339), methyl-p-hydroxybenzoate (E218), propyl p-hydroxybenzoate (E216), strawberry flavour, aspartame (E951) and purified water.

**What Docosate Sodium Paediatric 12.5mg/5ml Oral Solution looks like and contents of the pack**

Docosate Sodium Paediatric 12.5mg/5ml Oral 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., 14D Wendover Road, Rackheath Industrial Estate, Norwich, NR13 6LH.

**Manufacturer:**

Laboratórios Basi – Indústria Farmacêutica, S.A.  
Parque Industrial Manuel Lourenço Ferreira, Lotes 15 e 16 3450-232 Mortágua, Portugal.

**Date of Leaflet Preparation:** November 2015