


<i>Title:</i>	Typharm Docusate Sodium PIL	<i>Colours</i> <i>(Non printed)</i> 
<i>Ref:</i>	TDS/TY/P/50	
<i>Date:</i>	26/03/21	
<i>Size (mm):</i>	200x280mm	
<i>Modified:</i>	13/08/22	

## Package leaflet: Information for the patient

# Docusate Sodium Paediatric 12.5mg/5ml Oral Solution

## Docusate Sodium

**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 the patient gets 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 Paediatric is and what it is used for
2. What you need to know before the patient takes Docusate Sodium Paediatric
3. How to take Docusate Sodium Paediatric
4. Possible side effects
5. How to store Docusate Sodium Paediatric
6. Contents of the pack and other information

## 1. WHAT DOCUSATE SODIUM PAEDIATRIC IS AND WHAT IT IS USED FOR

### What Docusate Sodium Paediatric is

Docusate Sodium Paediatric contains the active substance docusate sodium. This medicine is a laxative. It belongs to a group of medicines called 'stool softeners'. Docusate Sodium Paediatric is used to treat constipation in children and infants 6 months and over.

### How Docusate Sodium Paediatric works

Docusate Sodium Paediatric softens the stools (faeces). It does this by increasing the amount of water within the stools (faeces). This makes the patient's bowel movements easier.

It helps the patient when they:

- Are constipated
- Have piles
- Have a tear in the lining of their anus (anal fissure)

### What is constipation?

Normal and regular bowel movement is important for most people. However, what is 'normal and regular' varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for the patient, it is best that their bowel movement has a regular pattern.

Constipation is an occasional problem for some people – for others, it may happen more often.

Constipation happens when the normal muscle actions in the bowel slow down.

The cause of constipation is often not known. It can be linked with:

- Pregnancy
- Lack of exercise
- Sudden change of diet
- A diet with not enough fibre
- Having to stay in bed for a long time
- Medicines such as morphine or codeine
- Loss of 'tone' of the bowel muscles in older people

Whatever the cause, constipation can be uncomfortable. It may make the patient feel bloated and heavy or generally 'off-colour'. Sometimes it causes headaches.

Try these healthy tips to help prevent constipation happening:

- Eat a balanced diet including fresh fruit and vegetables.
- Drink enough water so that you do not become dehydrated.
- Keep up your exercise and stay fit.
- Make time to empty your bowels when your body tells you.

## 2. WHAT YOU NEED KNOW BEFORE THE PATIENT TAKES DOCUSATE SODIUM PAEDIATRIC

### Do not give Docusate Sodium Paediatric if:

- The patient has stomach pains
- The patient feels sick or has been sick in the last 24 hours
- The patient has a blockage in their intestine (intestinal obstruction)
- The patient is allergic to docusate sodium or any of the other ingredients of this medicine (listed in section 6).
- The patient is intolerant to any sugars such as sorbitol. Docusate Sodium Paediatric contains sorbitol.
- The patient is taking mineral oil laxative such as liquid paraffin.

Do not give this medicine if any of the above applies to the patient. If you are not sure, talk to the patient's pharmacist or doctor before giving this medicine.

### Warnings and precautions

As with all laxatives, do not give Docusate Sodium Paediatric every day for a long time.

Talk to the patient's doctor or pharmacist if:

- The patient ends up taking Docusate Sodium Paediatric every day
- The patient gets stomach pain which does not go away.

If any of the above applies to the patient (or you are not sure), talk to the patient's pharmacist or doctor. Docusate Sodium Paediatric should not be given to infants under the age of 6 months.

### Other medicines and Docusate Sodium Paediatric

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

Docusate Sodium Paediatric 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 Docusate Sodium Paediatric increases their effects.

### Taking Docusate Sodium Paediatric with food and drink

Docusate Sodium Paediatric can be taken with food and drink.

### Important information about some of the ingredients of Docusate Sodium Paediatric 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 (5ml). May cause allergic reactions (possibly delayed).

### Docusate Sodium Paediatric contains sorbitol

This medicine contains 1290 mg of sorbitol in each dose (5 ml). 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.

### Docusate Sodium Paediatric 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 Paediatric 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 PAEDIATRIC

Always give this medicine exactly as described in this leaflet or as the patient's pharmacist or doctor has told you. Check with the patient's pharmacist or doctor if you are not sure.

### How much to take

Infants aged 6 months to 2 years

- The recommended dose for infants aged over 6 months is one 5 ml spoonful three times a day.

Children aged 2 – 12 years

- The recommended dose for children aged 2-12 years is one to two 5 ml spoonfuls three times a day.

This medicine should not be given to infants under the age of 6 months.

Reduce the dose as the condition improves.

The patient should feel more comfortable within 1 to 2 days of treatment.

Talk to the patient's pharmacist or doctor if the patient ends up taking Docusate Sodium Paediatric every day.

### How to take

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.

### If the patient takes more Docusate Sodium Paediatric than they should

If the patient takes more Docusate Sodium Paediatric 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 Paediatric

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. The following side effects may occur with this medicine:

### Talk to the patient's pharmacist or doctor if the patient gets any of the side effects listed below:

**Rare:** affects fewer than 1 in 1,000 people

- Feeling sick (nausea)
- Diarrhoea
- Stomach cramps

**Not known:** frequency cannot be estimated from the available data

- Skin rash
- Pruritus (itching)

Talk to the patient's doctor or pharmacist if the patient gets any of the side effects listed above.

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, talk to the patient's doctor or pharmacist.

### Reporting of side effects

If the patient gets any side effects, talk to the patient's 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 PAEDIATRIC

This medicinal product does not require any special storage conditions.

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 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 Paediatric contains

- The active substance is docusate sodium. Each 5 mL of the solution contains 12.5 mg of docusate sodium.
- The other ingredients are sorbitol (E420), glycerol (E422), povidone, monosodium phosphate dihydrate, disodium phosphate dodecahydrate, methyl p-hydroxybenzoate (E218), propyl p-hydroxybenzoate (E216), strawberry flavour, aspartame (E951) and purified water.

### What Docusate Sodium Paediatric looks like and contents of the pack

Docusate Sodium Paediatric 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, Unit 1, 39 Mahoney Green, Rackheath, Norwich, NR13 6JY.

### Manufacturer

Laboratórios Basi – Industria Farmacêutica, S.A., Parque Industrial Manuel Lourenco Ferreira, Lotes 8, 15 e 16 3450-232 Mortágua, Portugal

**This leaflet was last revised in August 2022.**