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

Docusate 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. Docusate 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 Docusate Sodium Paediatric 12.5mg/5ml Oral Solution

- if the patient is allergic to docusate 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.

Warnings and precautions

Talk to the patient's doctor or pharmacist before the patient starts taking Docusate Sodium Paediatric 12.5mg/5ml Oral Solution.

- Docusate 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 Docusate 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.

Docusate 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 Docusate Sodium Paediatric 12.5mg/5ml Oral Solution increases their effects.

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

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

Important information about some of the ingredients of Docusate Sodium

Paediatric 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 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 the patient 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. Docusate sodium may cause an unpleasant aftertaste or burning sensation. This may be minimised by drinking plenty after taking the solution.

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

If the patient takes more Docusate 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 Docusate 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.

If any of the following happen, stop taking Docusate Sodium Paediatric 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 the patient needs to take a laxative every day, or if the patient has a persistent stomach ache, they must see their 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 the patient notices any side effects not listed in this leaflet, please tell 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 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 12.5MG/5ML ORAL SOLUTION

This medicinal product does not require any special storage condition. 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 12.5mg/5ml Oral Solution contains

- The active substance is docusate sodium (12.5mg/5ml)
- 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 12.5mg/5ml Oral Solution looks like and contents of the pack

Docusate 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., 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