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Package leaflet: Information for the user

Docusate Sodium Adult 50mg/5ml Oral Solution

Read all of this leaflet carefully before you start 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 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.

Take special care with 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 which may cause allergic reactions, possibly delayed.

Docusate Sodium Adult 50mg/5ml Oral Solution contains glycerol. It may cause headache, stomach upset and diarrhoea.

Docusate Sodium Adult 50mg/5ml Oral Solution contains sorbitol. Each 5ml dose contains 0.9g of sorbitol. If you have been told by your doctor that you have an intolerance to sorbitol, contact your doctor before you take this medicine.

Docusate Sodium Adult 50mg/5ml Oral Solution contains aspartame which is a source of phenylalanine. May be harmful for people with phenylketouria.

Docusate Sodium Adult 50mg/5ml Oral Solution contains propylene glycol which may cause alcohol-like symptoms.

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 doses (50ml). Reduce the dose as the condition improves.

If you have been told to take Docusate Sodium Adult 50mg/5ml Oral Solution during a stomach X-ray, you should take eight 5ml spoonfuls. Your doctor will tell you exactly when to take the 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 your 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 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.

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 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 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, sodium acid phosphate (E339), sodium phosphate (E339), methyl p-hydroxybenzoate (E218), propyl p-hydroxybenzoate (E216), strawberry flavour, propylene glycol (E1520), aspartame (E218), sodium benzoate (E212), citric acid anhydrous (E330) 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 a amber glass bottle of 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.

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