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## Package leaflet: Information for the patient

# Docusol Constipation Relief 50 mg/5 ml Solution

## Docusate 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 pharmacist or doctor 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 pharmacist or doctor. 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.
- The full name of your medicine is Docusol Constipation Relief 50 mg/5 ml Solution. In this leaflet the shorter name Docusol Solution is used.

### What is in this leaflet:

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

## 1. WHAT DOCUSOL SOLUTION IS AND WHAT IT IS USED FOR

### What Docusol Solution is

Docusol Solution contains the active substance docusate sodium. This medicine is a laxative. It belongs to a group of medicines called ‘stool softeners’. Docusol Solution is used to prevent and treat constipation in adults and children aged over 12 years.

### How Docusol Solution works

Docusol Solution softens the stools (faeces). It does this by increasing the amount of water within the stools (faeces). This makes your bowel movements easier and reduces the strain required to pass stools.

It helps you when:

- You are constipated
- You have piles
- You have a tear in the lining of your 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 you, it is best that your 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 you 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 TO KNOW BEFORE YOU TAKE DOCUSOL SOLUTION

### Do not take Docusol Solution if:

- You have stomach pains
- You feel sick or have been sick in the last 24 hours
- You have a blockage in your intestine (intestinal obstruction)
- You are allergic to docusate sodium or any of the other ingredients of this medicine (listed in section 6).
- You are intolerant to any sugars such as sorbitol. Docusol Solution contains sorbitol.
- You are taking a mineral oil laxative such as liquid paraffin.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist or doctor before taking this medicine.

### Warnings and precautions

As with all laxatives, do not take Docusol Solution every day for a long time.

Talk to your pharmacist or doctor if:

- You end up taking Docusol Solution every day.
- You get stomach pain which does not go away.

If any of the above applies to you (or you are not sure), talk to your pharmacist or doctor.

This medicine is not suitable for children aged 6 months to 12 years but a suitable alternative, Docusol Paediatric Solution is available.

### Other medicines and Docusol Solution

Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines.

Docusol Solution should not be taken if you are already taking a mineral oil laxative such as liquid paraffin.

If you are taking an anthraquinone laxative such as senna, you will need to reduce the dose as Docusol Solution increases their effects.

### Taking Docusol Solution with food and drink

Docusol Solution can be taken with food and drink.

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your pharmacist or doctor for advice before taking this medicine.

### Important information about some of the ingredients of Docusol Solution

#### Docusol Solution 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 (5 ml). May cause allergic reactions (possibly delayed).

### Docusol Solution contains sorbitol.

This medicine contains 1290 mg of sorbitol in each dose (5 ml). Sorbitol is a source of fructose. If your doctor has told you that you (or your child) has an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

### Docusol Solution 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.

### Docusol Solution contains sodium benzoate.

This medicine contains 5 mg sodium benzoate in each dose (5 ml).

### Docusol Solution 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 DOCUSOL SOLUTION

Always take this medicine exactly as described in this leaflet or as your pharmacist or doctor has told you. Check with your pharmacist or doctor if you are not sure.

### How much to take

Adults and children aged over 12 years

- The recommended dose is two 5ml spoonfuls three times a day.
- The maximum daily dose is six 5ml spoonfuls (30ml).
- Reduce the dose as the condition improves.

Do not give Docusol Solution to children aged 12 years and under. You should feel more comfortable within 1 to 2 days of treatment. Talk to your pharmacist or doctor if you end up taking Docusol Solution every day.

### How to take

Swallow each dose followed by plenty of water or flavoured drink e.g. milk or orange juice.

### If you take more Docusol Solution than you should

If you accidentally take more Docusol 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 Docusol 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 pharmacist or doctor.

## 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 Docusol Solution and talk to your pharmacist or 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)

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, talk to your pharmacist or doctor.

### Reporting of side effects

If you get any side effects, talk to your doctor pharmacist or doctor. 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 DOCUSOL SOLUTION

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 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 Docusol Solution contains

- The active substance is docusate sodium. Each 5 mL of the solution contains 50 mg of docusate sodium.
- The other ingredients are sorbitol (E420), glycerol (E422), povidone, methyl p-hydroxybenzoate (E218), propyl p-hydroxybenzoate (E216), sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium benzoate, citric acid anhydrous, aspartame, strawberry flavour and purified water.

### What Docusol Solution looks like and contents of the pack

Docusol Solution is a clear liquid available in amber glass bottles of 125 ml and 300 ml with a plastic screw cap. Not all pack sizes may be marketed.

### 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 October 2023.