

DulcoEase[®]

100 mg Capsules

docusate sodium

Package Leaflet: Information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has 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 or pharmacist if you do not feel better or you feel worse
- The full name of your medicine is DulcoEase 100 mg Capsules. In this leaflet the shorter name DulcoEase is used

What is in this leaflet:

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

1. What DulcoEase Capsules is and what it is used for

What DulcoEase is

DulcoEase contains the active substance docusate sodium. This medicine is a laxative. It belongs to a group of medicines called 'stool softeners'.

- DulcoEase is used to treat constipation in adults and children 12 years and over

How DulcoEase works

DulcoEase softens the stools (faeces).

- It does this by increasing the amount of water within the stools (faeces)
- This makes your bowel movements easier

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 DulcoEase Capsules

Do not take DulcoEase 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 fructose or sorbitol. DulcoEase contains a small amount of 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 DulcoEase every day for a long time.

Talk to your pharmacist or doctor if:

- You end up taking DulcoEase 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.

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Other medicines and DulcoEase

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

Do not take DulcoEase together with a mineral oil laxative such as liquid paraffin.

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.

DulcoEase contains Sorbitol, Sunset**Yellow (E110), Propylene glycol and Sodium**

- This medicine contains approximately 19.3 mg of sorbitol in each 100mg capsule which is equivalent to 1.38mg/kg. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have 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.
- DulcoEase contains the colouring Sunset Yellow E110. This may cause an allergic reaction
- This medicine contains 11.5 mg propylene glycol in each capsule which is equivalent to 0.49mg/kg.
- This medicine contains less than 1mmol sodium per capsule, that is to say essentially 'sodium free'.

3. How to take DulcoEase Capsules

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 12 years and over

- The recommended dose is to start with one capsule 3 times a day. Then take more or less if you need to
- Do not take more than one capsule 5 times a day

Do not give DulcoEase to children under 12 years of age.

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

Talk to your pharmacist or doctor if you end up taking DulcoEase every day.

How to take

Swallow each capsule whole with water.

If you take more DulcoEase than you should

If you take more DulcoEase than you should, drink lots of water. Then see a doctor or go to the nearest hospital casualty department straight away.

4. Possible side effects

Like all medicines, DulcoEase can cause side effects, although not everybody gets them. The following side effects may occur with this medicine:

Talk to your doctor or pharmacist if you get 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 your doctor or pharmacist if you get any of the side effects listed above.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 DulcoEase Capsules

- 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 carton and blister label after EXP. The expiry date refers to the last date of that month
- Do not store above 25°C
- Store in the original package in order to protect from moisture
- Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Contents of the pack and other information**What DulcoEase contains**

- The active substance is docusate sodium. Each capsule contains 100 mg of docusate sodium
- The other ingredients are: macrogol 400, propylene glycol, gelatin, glycerol, sorbitol (E420), titanium dioxide (E171), water, sunset yellow (E110), and quinoline yellow (E104)

What DulcoEase Capsules look like and contents of the pack

DulcoEase 100 mg Capsules are yellow and white coloured soft, oval capsules. They are available in blister packs of 10, 30 and 60 capsules.

The Marketing Authorisation is held by:

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DulcoEase Capsules are manufactured at:
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5048 AS Tilburg, Netherlands.

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