PATIENT INFORMATION LEAFLET

Docusate Sodium 100 mg Capsules

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 prescribed 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.

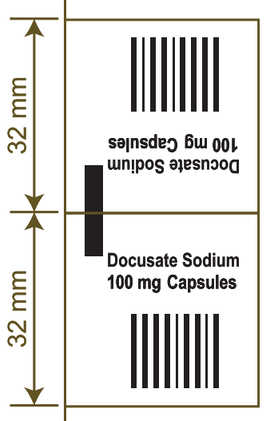
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

You must talk to a doctor if you do not feel better or if you feel worse.

The name of your medicine is Docusate Sodium 100 mg Capsules. It will be referred to as Docusate Sodium Capsules for ease of use hereafter.

In this leaflet:

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



1. What Docusate Sodium Capsules are and what they are used for

Docusate Sodium Capsules contain the active substance docusate sodium, it is one of a group of medicines called 'laxatives'. They are usually taken to prevent and treat constipation that has lasted for a long time. It may also be taken during certain types of stomach X-rays, or to help you go to the toilet if you have piles (haemorrhoids).

2. What you need to know before you take Docusate Sodium Capsules

Do not take Docusate Sodium Capsules:

- 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
- if you are feeling sick, or have been sick in the last 24 hours
- if you have a blocked bowel (intestinal obstruction)
- if you have been told you are unable to take a sugar called fructose.

Docusate Sodium Capsules contain sorbitol and is therefore unsuitable for you.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Docusate Sodium Capsules:

- if you need to take a laxative every day
- if you have regular or constant stomach pain

Other health conditions should be excluded before taking this medicine.

The treatment of constipation with Docusate Sodium Capsules is only additional to a healthy lifestyle and diet (such as increased intake of fluids, dietary fibre and exercise).

Other medicines and Docusate Sodium Capsules

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

Tell your doctor if you are taking any of the following medicines:

- Mineral Oil
- Any other medicine, including medicines obtained without a prescription.

Docusate Sodium Capsules with food and drink

Docusate Sodium Capsules can be taken with or without food.

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 doctor or pharmacist for advice before taking this medicine.

Pregnancy

The safety of Docusate Sodium Capsules during pregnancy has not yet been proven.

Breast-feeding

Docusate sodium is excreted in breast milk and should therefore be used with caution in breast-feeding mothers.

Docusate Sodium Capsules contain sorbitol and propylene glycol

- Do not take Docusate Sodium Capsules if you are intolerant to any sugars such as fructose or sorbitol. This medicine contains approximately 38.94 mg of sorbitol in each capsule.
- This medicine contains 6 mg propylene glycol in each capsule.

3. How to take Docusate Sodium Capsules

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

The recommended dose in adults and adolescents (12 years and older) is:

- Maximum dose is 5 capsules although you may need less
- Take your capsules one at a time at regular intervals through out the day
- Swallow Docusate Sodium Capsules whole with a drink of water
- Reduce the dose as your condition gets better
- If you have been told to take Docusate Sodium Capsules during a stomach X-ray, you should take four capsules

Your doctor will tell you exactly when to take the capsules.

Use in children aged 0 to 11 years:

Docusate Sodium Capsules are not suitable for children under 12 years of age.

If you take more Docusate Sodium Capsules than you should:

If you take more Docusate Sodium Capsules than you should, drink lots of water and immediately go to your doctor or the nearest hospital casualty department.

If you forget to take Docusate Sodium Capsules:

Do not take a double dose to make up for a forgotten dose.

If you stop taking Docusate Sodium Capsules:

If you have any further questions on the use of this medicine, ask your 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 Capsules and tell your doctor as soon as possible:

Rare (may affect up to 1 in 1,000 people)

- Diarrhoea
- Feel sick
- Stomach cramps

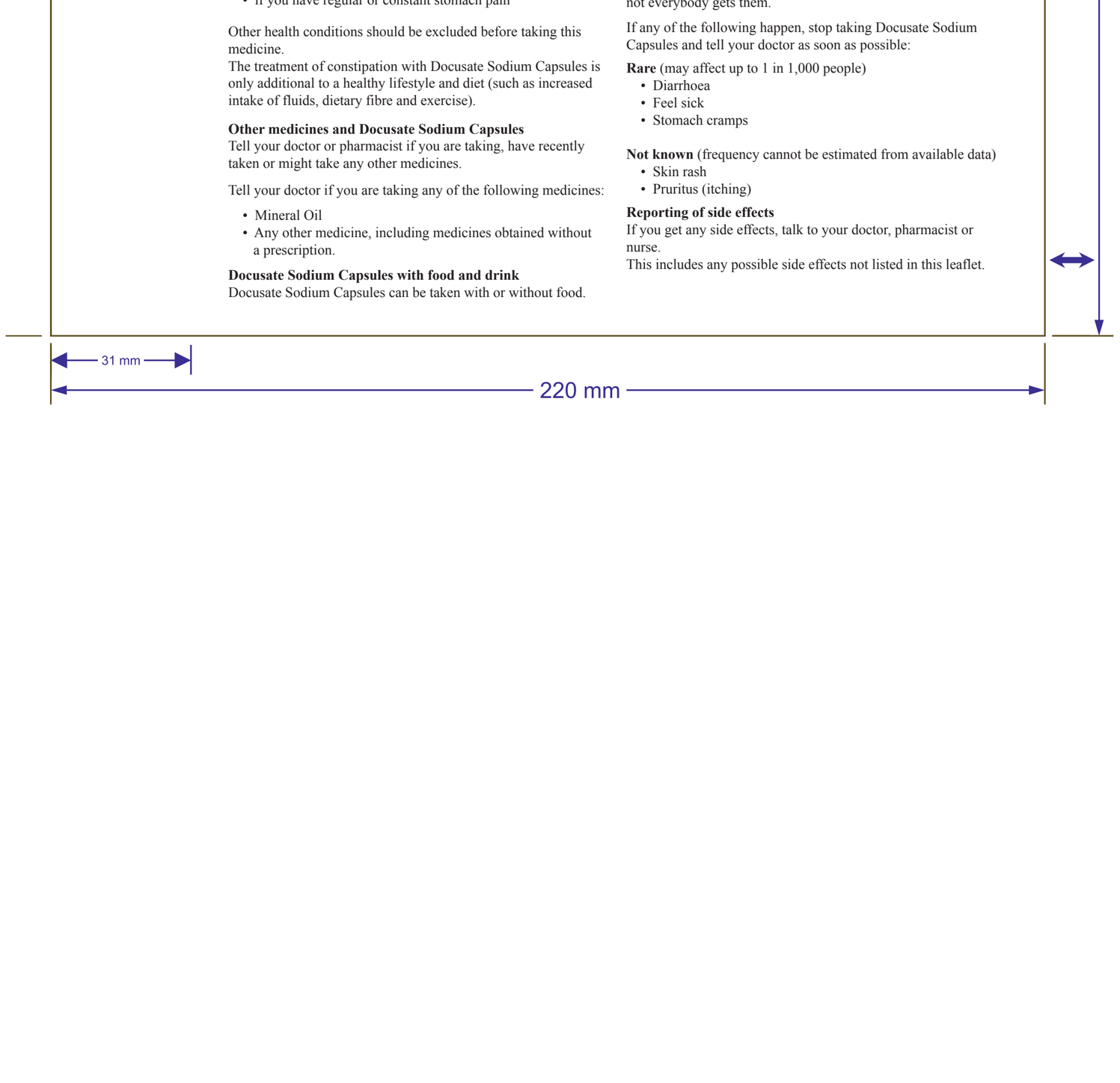
Not known (frequency cannot be estimated from available data)

- Skin rash
- Pruritus (itching)

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, Website: 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 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 label after EXP. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions. Store in original package in order to protect from moisture.

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 protect the environment.

6. Contents of the pack and other information

What Docusate Sodium Capsules contain:
Each capsule contains 100 mg docusate sodium.
The other ingredients are: macrogol 400, propylene glycol, gelatin 200 bloom, purified water, glycerol, sorbitol, titanium dioxide (E171), quinoline yellow (E104).

What Docusate Sodium Capsules look like and contents of the pack:
Docusate Sodium Capsules are approximately 13mm long and 7mm wide yellow opaque, oval, soft gelatin capsule containing clear to pale yellow liquid fill.
Docusate Sodium Capsules are available in 200cc Multilayered HDPE Bottle with 38mm – SP 400 Neck & 38mm PPCR closure with liner containing 250 capsules, 90cc Multilayered HDPE Bottle with 38mm – SP 400 Neck & 38mm PPCR closure with liner containing 100 capsules or 40cc Multilayered HDPE Bottle with 33mm – SP 400 Neck & 33mm PPCR closure with liner containing 30 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
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Manufacturer:
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For information in large print, Braille or on CD, email info@siinovia.com

