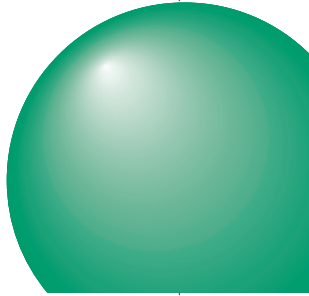


Package leaflet: Information for the user

Dioctyl[®]

100 mg capsules

Docusate sodium



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 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.

What is in this leaflet:

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

1. What Dioctyl is and what it is used for

Dioctyl contains 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 Dioctyl

Do not take Dioctyl:

- 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. Dioctyl contains sorbitol and is therefore unsuitable for you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dioctyl:

- 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 Dioctyl is only additional to a healthy lifestyle and diet (such as increased intake of fluids, dietary fibre and exercise).

Other medicines and Dioctyl:

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.

Dioctyl with food and drink

Dioctyl 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 Dioctyl 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.

Dioctyl contains sorbitol, sunset yellow (E110) and Propylene glycol

- Do not take Dioctyl if you are intolerant to any sugars such as fructose or sorbitol. This medicine contains approximately 26 mg of sorbitol in each capsule.
- Dioctyl contains the colouring Sunset Yellow E110. This may cause an allergic reaction.
- This medicine contains 11.5 mg propylene glycol in each capsule.

3. How to take Dioctyl

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 throughout the day
- Swallow Dioctyl capsules whole with a drink of water
- Reduce the dose as your condition gets better
- If you have been told to take Dioctyl 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:

Dioctyl is not suitable for children under 12 years of age.

If you take more Dioctyl than you should:

If you take more Dioctyl than you should, drink lots of water and immediately go to your doctor

or the nearest hospital casualty department.

If you forget to take Dioctyl:

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

If you stop taking Dioctyl:

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 Dioctyl 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)

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 Dioctyl

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the 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 Dioctyl contains

Each capsule contains 100 mg docusate sodium.

The other ingredients are: macrogol 400, propylene glycol, gelatin 175 bloom, purified water, glycerol, sorbitol, titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110), lecithin, isopropyl alcohol and medium-chain triglycerides.

What Dioctyl looks like and contents of the pack

Dioctyl are yellow and white soft, oval capsules. Dioctyl is available in blister packs containing 10, 20, 30, 40 or 50 capsules and in plastic containers with 30 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Teofarma S.r.l.

Via F.lli Cervi, 8

27010 Valle Salimbene (PV) - Italy

This leaflet was last revised in August 2023.

If this leaflet is difficult to read and you would like it in a different format, please contact Teofarma S.r.l. Via F.lli Cervi, 8, Valle Salimbene. PV. 27010. Italy.