dioctyl ®

100 mg capsules

Docusate sodium Oral use

Read the package leaflet before use.

For the prevention and treatment of constipation

Dose: **Adults and Elderly** - Up to five capsules per day. The capsules should be swallowed whole with a glass of water.

Children - Not recommended.
See the package leaflet for further information.

Each capsule contains 100 mg docusate sodium.

If laxatives are needed every day, or if you have persistent stomach pain, talk to your doctor.

Keep out of the sight and reach of children.

PL 16250/0014 (P)

Do not store above 25°C.
Store in the original package in order to protect from moisture

UK Only

5 015366 000262

D I O C T Y L

base label

The coding text detailed below will be added on the production line along with the actual coding data.

LOT:

EXP:

CUSTOMER TO COMPLETE AT PROOF STAGE

Please note: proofs are submitted to enable customers to check all details. We will accept no responsibility for any errors that have been passed by the customer.

Approved (including applicator direction) ☐

Approved subject to alts ☐

Not approved ☐

(Please tick as appropriate and indicate clearly, in red pen, any alterations required)

Signed

Date / /

FORM REF. CPL/8

Customer	Wasdell Packaging Limited
Product Code	PATLB01-1 DIOCTYL 100mg Capsules
Product Title	10pp FaF with braille
Colours	Black Green 340 Braille All over varnish
Dimensions	60 x 111mm (final size)
Job No.	108206
Date	05.06.23
Version	4
Artwork By	SW

Label applicator direction

Please note that this proof may include the use of our trade mark/imprint. This fulfils the legal need to identify us as the printers of the leaflet and helps to protect our product and yours from counterfeit production. Where space is limited it is placed within the glued strip area, which means that in normal use it will not be visible to the product user.
If this proof is not a press proof it cannot be judged for colour accuracy; it will be representative only.

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 everyday
- 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
- Swallow Dioctyl capsules whole with a drink of water
- Take your capsules one at a time at regular intervals throughout the day
- 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 yellowcard 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 shown on the label 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 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 containing10, 20, 30, 40 or 50 capsules and in plasticcontainers with 30 or 100 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:
Teofarma S.r.l.
Via F.lli Cervi, 8
27010 Valle Salimbene (PV) - Italy

Manufacturer:
Teofarma S.r.l.
Viale Certosa, 8/A - 27100 Pavia - Italy

This leaflet was last revised in September 2023.

Hard to read? Send an e-mail to servizioclienti@teofarma.it for help.

dioctyl ®

100 mg capsules

Docusate sodium Oral use

For the prevention and treatment of constipation.

Dose: **Adults and Elderly** - Up to five capsules per day. he capsules should be swallowed whole with a glass of water.

Children - Not recommended.
The other ingredients are sorbitol, sunset yellow (E110) and propylene glycol.

Each capsule contains 100 mg docusate sodium.

If laxatives are needed every day, or if you have persistent stomach pain, talk to your doctor.
Keep out of the sight and reach of children.

PATLB01-1 **100 capsules**

Do not remove from container. See package leaflet for further information. Read the package leaflet before use.