

## 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.

### **Diocetyl with food and drink**

Diocetyl 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 Diocetyl 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.

### **Diocetyl contains sorbitol and sunset yellow (E110)**

- Diocetyl contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Diocetyl contains the colouring Sunset Yellow E110. This may cause an allergic reaction.

## **3. How to take Diocetyl**

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

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

### **If you take more Diocetyl than you should:**

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

### **If you forget to take Diocetyl:**

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

### **If you stop taking Diocetyl:**

If you have any further questions on the use of this medicines, 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
- Skin rash

### **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](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 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, 100 or 250 capsules. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire SL1 3WE, UK

**This leaflet was last revised in April 2019.**

If this leaflet is difficult to read and you would like it in a different format, please contact UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK.