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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

nformation 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 Diocty , 4. Possible side effects 5. How to store Dioctyl 6. Contents of the pack and other information

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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

1. What Dioctyl is and what it is used for

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)

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sugar called fructose. Dioctyl contains sorbitol and is therefore unsuitable for you Warnings and precautions Talk to your doctor or pharmacist before taking

• if you have been told you are unable to take a

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

Page 4

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 yello

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(EII0) and Propylene glycol

sugars such as fructose or sorbitol.

This medicine contains approximately 26 mg of sorbitol in each capsule. Dioctyl contains the colouring Sunset Yellow

EIIO. 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

• Do not take Dioctyl if you are intolerant to any • Reduce the dose as your condition gets better

dioctyl

100 mg capsules

Docusate sodium Oral use

Dose: Adults and Elderly - Up to five

capsules per day. he capsules should be

swallowed whole with a glass of water.

Children - Not recommended.

(EII0) and propylene glycol.

doctor

PATLB01-1

For the prevention and treatment of constipation.

The other ingredients are sorbitol, sunset yellow

Each capsule contains 100 mg docusate sodium.

If laxatives are needed every day, or if you

have persistent stomach pain, talk to your

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    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
                                                               Diarrhoea
the capsules.
Use in children aged 0 to 11 years:

    Feel sick

    Stomach cramps

Dioctyl is not suitable for children under 12 years
of age.
                                                             from the available data
If you take more Dioctyl than you should:

    Skin rash

    Pruritus (Itching)

If you take more Dioctyl than you should, drink
lots of water and immediately go to your doctor
                                                             Reporting of side effects
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.
                                                             Play or Apple App Store.
4. Possible side effects
Like all medicines, this medicine can cause side
                                                             5. How to store Dioctyl
effects, although not everybody gets them.
If any of the following happen, stop taking Dioctyl
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and tell your doctor as soon as possible: Rare: may affect up to 1 in 1,000 people

Not known: frequency cannot be estimated

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 <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA yellowcard in the Google

By reporting side effects you can help provide more information on the safety of this medicine.

Keep this medicine out of the sight and reach of Page 8

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 What Dioctyl contains:

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

Page 9

Dioctyl are yellow and white soft, oval capsules.

containing10, 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: Marketing Authorisation Holder Teofarma S.r.I. Via F.IIi Cervi, 8 27010 Valle Salimbene (PV) - Italy Manufacturer: Teofarma S.r.I. Viale Certosa, 8/A - 27100 Pavia - Italy

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Dioctyl is available in blister packs

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This leaflet was last revised in September 2023. Hard to read? Send an e-mail to servizioclienti@teofarma.it for help.

Keep out of the sight and reach of children. 100 capsules

Page 1

Each capsule contains 100 mg docusate sodium.

sdell Packaging Limited				
LB01-1 DIOCTYL 100mg Capsules				
p FaF with braille				
k Green 340 Braille All over varnish				
x 111mm (final size)				
206				
06.23	Label applicator direction			
	Here the second			
	\rightarrow			
int. This fulfils the legal need to identify us as the counterfeit production. Where space is limited it t will not be visible to the product user.				



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