

PACKAGE LEAFLET:

INFORMATION FOR THE USER

Dioralyte Natural/Citrus/Blackcurrant Powder for Oral Solution

glucose, sodium chloride, potassium chloride, disodium hydrogen citrate

Read all of this leaflet carefully before you start taking Dioralyte because it contains important information for you.

Always take this medicine exactly as described in this

leaflet or as your doctor or pharmacist has 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 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 after 24-36 hours.

In this leaflet:

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

1. What Dioralyte is and what it is used for

Dioralyte is an oral rehydration therapy containing a balanced combination of electrolytes which include glucose, sodium chloride, potassium chloride and disodium hydrogen citrate.

It is recommended for the replacement of essential water and salt loss which can happen for various reasons including when you have diarrhoea.

2. What you need to know before you take Dioralyte

Do not take Dioralyte and talk to your doctor or pharmacist if:

- You are allergic (hypersensitive) to glucose, sodium chloride, potassium chloride and disodium hydro-gen citrate or any of the other ingredients of Dioralyte (see Section 6: Contents of the pack and other information) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Your bowel is partially or fully blocked (called ‘intestinal obstruction’)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Dioralyte.

Warnings and precautions

Take special care with Dioralyte

Check with your doctor or pharmacist before taking this medicine if:

- ▲ The child taking the medicine is under 24 months
- ▲ The diarrhoea has lasted for more than 24 to 36 hours, you may need other treatment
- ▲ You are on a low potassium or low sodium diet
- ▲ You have liver or kidney disease
- ▲ You have diabetes

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Dioralyte.

Children

For infants under 24 months use only on medical advice.

Infants under the age of 24 months that have diarrhoea should be seen by a doctor as soon as possible.

Other medicines and Dioralyte

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Dioralyte can affect the way some other medicines work. Also some medicines can affect the way Dioralyte works.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding. This includes if you are planning to get pregnant or think you that you might be pregnant.

Important information about some of the ingredients of Dioralyte

This medicine contains glucose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine

Dioralyte contains sodium

This medicine contains 278 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 13.9% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Dioralyte

If you are not sure how to take this medicine, check with your doctor or pharmacist.

Preparing this medicine:

Dioralyte must be mixed with water before taking.

- Prepare the solution just before it is going to be taken. Do not make in advance. you are giving it to a baby over the course of the day, you can keep the drink in a refrigerator for up to 24 hours.
- Only dissolve the powder in water. Do not dissolve in anything else.
- Always use water that has been freshly boiled and cooled for babies aged 3 months to 1 year.

If your child is under 24 months talk to your doctor before using Dioralyte.

Directions:

- 1) Empty the contents of 1 sachet into a glass
- 2) Add 200 ml (7 fl oz) of water
- 3) Stir until the powder dissolves

When your medicine is fully dissolved, the drink will be a colourless solution.

Do not use more or less than 200 ml of water. If you do, the drink will become too weak or too strong. It will not work as well. You may also upset the balance of salts in your body.

How many sachets to take

- If you are being sick (vomiting) take the medicine in small sips
- If you have diarrhoea, it is best not to eat during the early stages. If diarrhoea lasts for more than 24 to 36 hours see your doctor
- If you are elderly and/or suffer from liver or kidney disease, talk to your doctor before using Dioralyte
- If diarrhoea persists for more than 24 to 36 hours the patient should be seen by a doctor.
- Do not exceed the maximum daily dose of 14 sachets.
- The product should not be used for more than 5 days.

Adults including elderly persons:

- One or two sachets after each loose stool.

Children:

- One sachet after every loose stool.

Infants under 24 months

Use only on medical advice.

This medicine should only be given under the guidance of a doctor.

- The doctor will calculate how much to give your baby, depending on how much they weigh. This is usually about one to one and a half times the amount of fluid your baby normally has in 24 hours.
- Initially, if you are bottle feeding or giving other foods this should be stopped.
- If you are breast feeding, continue to feed normally. Your baby may need less breast milk so you may need to express some of your milk.
- If your baby is being sick (vomiting), you can give 5-10ml (one or two teaspoons) every 5 minutes. This can be gradually increased until they are able to drink normally.

If you take more Dioralyte than you should

Dioralyte is not normally harmful if you take more than you should. However, if large amounts are taken, you should talk to a doctor or go to a hospital straight away. This is particularly important if it is a child or baby or if you have severe liver or kidney problems. Take the medicine pack with you.

If you forget to take your Dioralyte

Do not take a double dose to make up for a forgotten dose. Take the next dose when you need to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Dioralyte can cause side effects, although not everybody gets them. However, if you notice anything unusual, talk to your doctor or pharmacist. You should not normally have any side effects.

Stop taking Dioralyte and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

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: HPRA Pharmacovigilance. Website:

www.hpra.ie

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

5. How to store Dioralyte

Keep this medicine out of the sight and reach of children. Do not use Dioralyte after the expiry date which is stated on the carton and sachet 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. The drink should be made up just before it is going to be taken. Throw away any remaining drink after 1 hour (or 24 hours if stored in a refrigerator). Do not throw away 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 Dioralyte contains

The active substances are glucose, sodium chloride, potassium chloride and disodium hydrogen citrate. Other Ingredients include: colloidal anhydrous silica, saccharin sodium, lemon/lime flavour (contains sulphur dioxide (E220), citrus packs only), blackcurrant flavour (contains ethanol, blackcurrant packs only).

Dioralyte Blackcurrant Powder contains small amounts of ethanol (alcohol), less than 100mg per dose.

Dioralyte Citrus Powder contains sulphur dioxide. Sulphur dioxide may rarely cause severe hypersensitivity reactions and bronchospasm.

What Dioralyte looks like and contents of the pack

Dioralyte® Natural/Citrus/Blackcurrant is supplied in foil/laminate sachets available in pack sizes of 6 and

20. Each sachet contains enough powder to make a drink up with 200 ml (7 fl oz) of water.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

Manufacturer

SIDEFARMA - Sociedade Industrial de Expansão Farmacêutica, SA Rua da Guiné, 26 2689 - 514 Prior Velho Portugal

For any information about this medicine, please contact the Marketing Authorisation Holder:

Phoenix Labs

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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