

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Dioralyte Rebalance 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 Rebalance because it contains important information for you.

Always take this medicine exactly as described in this leaflet.

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

1. What Dioralyte Rebalance is and what it is used for

Dioralyte Rebalance 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.

It should not be used in infants under 24 months without medical advice.

2. What you need to know before you take Dioralyte Rebalance

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

You are allergic (hypersensitive) to glucose, sodium chloride, potassium chloride and disodium hydrogen citrate or any of the other ingredients of Dioralyte Rebalance (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

Warnings and precautions

You must check with your doctor or pharmacist before taking this medicine if:

- ▲ The child taking the medicine is under 24 months old
- ▲ 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

You should not use Dioralyte Rebalance without medical advice if any of the above apply to you.

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

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.

Pregnancy and breast-feeding

Use only on medical advice if you are pregnant or breastfeeding.

Important information about some of the ingredients of Dioralyte Rebalance

- 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
- This medicine contains 278.6 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.
- Dioralyte Rebalance Blackcurrant contains 0.32mg of alcohol (ethanol) in each sachet. The amount in 1 sachet of this medicine is equivalent to less than 1ml beer or 1ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- Dioralyte Rebalance Citrus contains sulphur dioxide which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to take Dioralyte Rebalance

Always take this medicine exactly as described in this leaflet.

The recommended dose

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.
- 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 breastfeeding, 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.

How to take this medicine

- Dioralyte Rebalance must be mixed with water only before taking.
- Prepare the solution just before it is going to be taken. Do not make in advance.
- If refrigerated, the solution may be stored for up to 24 hours, otherwise any solution remaining an hour after reconstitution should be discarded.

Directions for reconstitution:

- 1) Empty the contents of 1 sachet into a glass
- 2) Add 200 ml (7 fl oz) of fresh drinking water. For infants under 1 year and where fresh drinking water is not available, the water should be freshly boiled then cooled.
- 3) Stir until the powder dissolves. When your medicine is fully dissolved, the drink will be a colourless solution.
- 4) The solution must not be boiled after reconstitution.

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.

Advice on taking sachets:

- 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
- Do not exceed the maximum daily dose of 14 sachets.
- The product should not be used for more than 5 days.

If you take more Dioralyte Rebalance than you should

Dioralyte Rebalance 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 Rebalance

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, you should consult your doctor or pharmacist.

4. Possible side effects

Like all medicines, Dioralyte Rebalance 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 Rebalance 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 or pharmacist. 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 Rebalance

Keep this medicine out of the sight and reach of children. Do not use Dioralyte Rebalance 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 reconstituted solution should be used within 1 hour but may be stored for up to 24 hours in a refrigerator at 2-8°C.

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 Rebalance 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).

What Dioralyte Rebalance looks like and contents of the pack

Dioralyte Rebalance Natural/Citrus/Blackcurrant is supplied in foil/laminate sachets available in pack sizes of 6 and 14. 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, 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

Tel: +353 1 5742410

Email: medicalinformation@phoenixlabs.ie

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.

This leaflet was last revised in December 2024.