

Package leaflet: Information for the User

Dioralyte Natural/Citrus/Blackcurrant Sachets

3.56g/470mg/300mg/530mg,

Powder for oral solution

Glucose, sodium chloride, potassium chloride, disodium hydrogen citrate

SANOFI

Is this leaflet hard to see or read? Phone 0800 035 2525 for help



Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Dioralyte Natural/Citrus/Blackcurrant Sachets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after using this medicine for 24-48 hours.
- If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Dioralyte is and what it is used for
2. Before you take Dioralyte
3. How to take Dioralyte
4. Possible side effects
5. How to store Dioralyte
6. Further information

1. What Dioralyte is and what it is used for



The name of your medicine is Dioralyte Natural/Citrus/Blackcurrant Sachets (called Dioralyte throughout this leaflet). Dioralyte works by replacing the water and salts lost from your body when you have diarrhoea. It contains glucose and salts (these are sodium chloride, potassium chloride and disodium hydrogen citrate). The powder is mixed with water before taking.

2. 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 hydrogen citrate or any of the other ingredients of Dioralyte (see Section 6: Further 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.



Take special care with Dioralyte. Check with your doctor or pharmacist before taking this medicine if:

- ▲ The child taking the medicine is under 2 years old
- ▲ The diarrhoea has lasted for more than 24-48 hours, you may need other treatment

- ▲ You have chronic or persistent diarrhoea
- ▲ 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.

If nausea and vomiting are present with the diarrhoea, small but frequent amounts should be drunk at first.



Taking other medicines

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 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, contact your doctor before taking this medicine.

This medicine contains approximately 300 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 16% of the recommended maximum daily dietary intake of sodium for an adult.

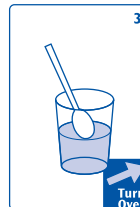
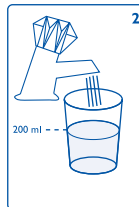
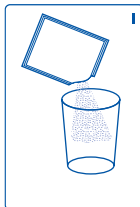
This medicine contains 156 mg potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take Dioralyte

Always use Dioralyte exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Preparing this medicine

- Dioralyte must be mixed with water before taking.
- Prepare just before the medicine is going to be taken. Do not make in advance. If 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 it in anything else
 - Use fresh drinking water for adults and children over 1 year old. If fresh water is not available, use water which has been freshly boiled and cooled
 - Always use water which has been freshly boiled and cooled for babies aged 3 months to 1 year



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 take the medicine in small sips
- It is best not to eat during the early stages of diarrhoea
- If the diarrhoea lasts for more than 24 to 48 hours see your doctor

Adults (including the elderly)

- One or two sachets after each loose stool

Children

- One sachet after each loose stool

Babies up to 2 years old

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
- Ask your doctor or pharmacist if you are not sure how much to give
- **If your baby is being sick**, you can give 5-10 ml (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 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.

United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Malta

You can also report side effects directly via ADR Reporting.

Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Dioralyte

Keep 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).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Dioralyte contains

- The active substances are glucose, sodium chloride, potassium chloride and disodium hydrogen citrate.
- The other ingredients are saccharin sodium, silicone dioxide. The citrus version also contains lemon and lime flavour, the blackcurrant version also contains blackcurrant flavour

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

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Manufacturer

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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.

This leaflet was last revised in August 2020.

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