PACKAGE LEAFLET: INFORMATION FOR THE USER **Dioralyte Relief Blackcurrant Dioralyte Relief Raspberry** 6.0g/580mg/350mg/300mg, **Powder for oral solution**

Pre-cooked rice powder, sodium citrate, sodium chloride, potassium chloride



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 Relief Blackcurrant/Raspberry 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 36 hours.
- If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

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



The name of your medicine is Dioralyte Relief Blackcurrant/Raspberry (called Dioralyte Relief throughout this leaflet). Dioralyte Relief works by replacing the water and salts lost from your body when you have diarrhoea. It helps the watery stools return to normal.

It contains pre-cooked rice powder and salts (these are sodium citrate, sodium chloride and potassium chloride). The powder is mixed with water before taking.

2. Before you take Dioralyte Relief



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

You are allergic (hypersensitive) to pre-cooked rice powder, sodium citrate, sodium chloride, potassium chloride or any of the other ingredients of Dioralyte Relief (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')

You have severe kidney or liver disease
 You have something called 'phenylketonuria' (a rare illness passed on in families)
 The child taking the medicine is under 3 months old

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 Dioralyté Relief.



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

 A You have something called an 'electrolyte imbalance' (unusual levels of salts in your body)
 A You are on a low potassium or low sodium diet
 A The child taking the medicine is under 1 year old Infants under the age of 2 with diarrhoea should be seen by a health care provider as soon as possible. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Dioralyte Relief.



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 Relief can affect the way some other medicines work. Also some medicines can affect the way Dioralyte Relief 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 Relief

Dioralyte Relief contains 50 mg of aspartame in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a raré genetic disorder in which phénylalanine builds up because the body cannot remove it properly

Dioralyte Relief contains 2.5 vol % ethanol (alcohol). One dose contains 191 mg of ethanol, which is about the same amount of alcohol as 4 ml of beer or 1.7 ml of wine. This can be harmful to people with a drink problem. Also take this into account if you are pregnant, breast-feeding or giving this to a child, have liver disease or epilepsy.

This medicine contains 190 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 10 % 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 Relief

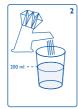
If you are not sure how to take this medicine, check with your doctor or pharmacist

Preparing this medicine

- Dioralyte Relief 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 look milky

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

Adults (including the elderly) and children over 1 year

One sachet after each loose stool

• You can take up to 5 sachets each day, for up to 3 to 4 days. Do not take more than 5 sachets in 24 hours

Babies aged 3 months to 1 year (to be given under the guidance of a doctor)

• The amount depends on how much the baby weighs. The usual dose is 150-200 ml of the drink for each kg of the baby's weight, each day. This can be given over 24 hours

 Give half the drink during the first 8 hours and the other half during the next 16 hours

 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 Relief than you should Dioralyte Relief 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. Take the medicine pack with you.

If you forget to take your Dioralyte Relief 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 Relief 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 Relief 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

Yellow Card scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Dioralyte Relief

Keep out of the sight and reach of children.

Do not use Dioralyte Relief 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 in a dry place below 25°C.

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 Relief contains

The active substances are pre-cooked rice powder,

sodium citrate, sodium chloride and potassium chloride The other ingredients are hypromellose, aspartame, blackcurrant flavour 501017 or raspherry flavouring 611417E, purified water and ethanol 96%

What Dioralyte Relief looks like and contents of the pack

Dioralyte Relief is available in pack sizes of 6. Packs of 6 may contain:

6 sachets of one flavour
4 sachets of blackcurrant flavour and 2 of raspberry (Blackcurrant & Raspberry)

• 4 sachets of raspberry flavour and 2 of blackcurrant (Raspberry & Blackcurrant)

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 Sanofi

410 Thames Valley Park Drive Reading, Berkshire, RG6 1PT, UK Tel: 0800 035 2525

email: uk-medicalinformation@sanofi.com

<u>Manufacturer</u>

Sanofi-Aventis Sp. z o.o., 52, Lubelska Str., 35-233 Rzeszów, Poland

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 revised in July 2020.



