ORS B PLUS SACHET

Dextrose Anhydrous/Trisodium Citrate Dihydrate/Potassium Chloride/Sodium Chloride (3375mg/725mg/375mg/650mg)

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What ORS B PLUS is used for

ORS B PLUS contains essential salts required by the body. It is used for treatment of replacement of water and electrolytes lost during moderate to severe diarrhoea.

How ORS B PLUS works

It replaces the water and some important salts that are lost from the body due to diarrhoea.

Before you use ORS B PLUS

-When you must not use it

Do not use this medicine if you suffer from any of the following:

- Kidney, liver or heart conditions
- Increased body potassium levels
- Problems with the amount of salt in your body
- Difficulty in passing urine
- High blood pressure
- Oedema (swelling of the limbs due to water retention)
- Severe vomiting
- Problems with products containing glucose

Pregnancy and lactation

Do not take ORS B PLUS if you are pregnant or think you may be pregnant.

Do not take ORS B PLUS if you are breast feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start use it

• Tell your doctor or pharmacist if you are allergic to any medicines.

 Tell your doctor and pharmacist what medications you are taking.

-Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from a pharmacy, medical hall or any other source.

How to use ORS B PLUS

Always take ORS B PLUS exactly as your doctor or pharmacist has told you.

Take one sachet and dissolve the contents in 250ml of cooled boiled water. It is to be taken orally.

Do not boil the solution and do not use if the contents in the sachet look wet.

Make and use fresh solutions each day. Discard unused solution at the end of each day.

Babies and small children should be given the solution slowly, in small amounts, as often as possible during the first 24 hours of diarrhoea.

ORS B PLUS should only be reconstituted with water at the volume stated. Do not increase or decrease the volume of water used.

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Children under 2 years:

250mL for the first 2 hours, 3 x 250mL can be taken a day.

Children 2-5 years:

 $3 \times 250 \text{mL}$ for the first 2 hours, $6 \times 250 \text{ mL}$ can be taken a day.

Adults:

4 x 250mL for the first two hours, 12 x 250mL can be taken throughout the day.

Infants and young children should be given small amounts of oral rehydration fluid administered frequently but slowly each time.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking your medicine for as long as your doctor or pharmacist recommends.

-If you use too much (overdose)

Taking too much of ORS B PLUS may cause the sodium and potassium level in the blood to be very high.

Go to the Emergency Department of your nearest hospital if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

-Things you must do

Talk to your doctor or pharmacist if your symptoms do not improve. Your doctor will assess your condition and decide if you should continue to take the medicine.

If you are seeking any other medical treatment, tell all the doctors, dentists and pharmacists that you are taking ORS B PLUS.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor or pharmacist.

Do not give ORS B PLUS to anyone else even if they have the same symptoms or condition as you.

Side effects

Like all medicines, ORS B Plus can cause side effects, although not everybody gets them. However, if you notice anything unusual, inform your doctor or pharmacist.

Side effects reported include Hypernatraemia, which is a high sodium level in the blood. Symptoms of

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hypernatraemia may include restlessness, weakness, thirst, swollen tongue, headache and hypotension.

Hyperkalaemia may occur after excessive intake, after the use of potassium-sparing diuretics, renal failure and acidosis. Symptoms include mental confusion, weakness, paralysis, hypotension, heart block and cardiac arrest.

Other side effects reported include nausea, vomiting, diarrhea and abdominal cramps.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of ORS B PLUS

-Storage

Keep all medicines out of the sight and reach of children.

Keep the medicines in a cool dry place where the temperature stays below 30°C. Protect from light.

Do not store in the bathroom or near a sink or on a window sill.

Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Do not take this medicine after the expiry date stamped on the pack. The expiry date refers to the last day of that month.

-Disposal

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.

Product Description

<u>-What it looks like</u>
A white and odourless, crystalline powder

-Ingredients

-Active ingredients are Potassium chloride 375mg, Dextrose anhydrous 3375mg, Sodium chloride 650mg and Sodium citrate 725mg.

-MAL number:

MAL19920763XZ

Manufacturer

Pharmaniaga Manufacturing Berhad (60016-D),

11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad (60016-D),

11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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