

Patient Information Leaflet

HYDRILAXE

Polyethylene Glycol, Sodium Chloride, Sodium Bicarbonate & Potassium Chloride Powder for Oral Solution

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

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

1. What HYDRILAXE is and what it is used for

The name of this medicine is HYDRILAXE sachet, powder for oral solution. It is a laxative for the treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age.

HYDRILAXE helps you to have a comfortable bowel movement even if you have been constipated for a long time. HYDRILAXE also works in very bad constipation called faecal impaction.

2. What you need to know before you take HYDRILAXE

Do not take HYDRILAXE if your doctor has told you that you have:

- a blockage in your intestine (gut obstruction, ileus)
- a perforated gut wall
- severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon
- an allergy to the active substances or any of the other ingredients of HYDRILAXE (listed in section 6).

Heart conditions

Follow the special instructions in section 3 if you are taking HYDRILAXE for faecal impaction

Other medicines and HYDRILAXE

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines, e.g. anti-epileptics, may not work as effectively during use with HYDRILAXE.

Pregnancy and breast feeding

HYDRILAXE can be taken during pregnancy and whilst breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, ask your pharmacist or doctor for advice before taking HYDRILAXE.

Driving and using machines

HYDRILAXE does not affect your ability to drive or use machines.

3. How to take HYDRILAXE

This medicine can be taken at any time with or without food.

Dissolve the content of each sachet in 125ml of water and drink.

Constipation:

A dose of HYDRILAXE is 1 sachet dissolved in 125 ml of water.

Take this 1-3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take HYDRILAXE for faecal impaction, it should be confirmed that you have this condition.

A dose of 8 sachets a day of HYDRILAXE is needed for the treatment of faecal impaction. Each sachet dissolved in 125ml of water. The 8 sachets should be taken within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 2 sachets in any one hour.

How to mix:

Open the sachet and pour the contents into a glass. Add about 125ml of water to the glass. Stir well until all the powder has dissolved and the HYDRILAXE solution is clear or slightly hazy, then drink it. If you are taking HYDRILAXE for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment:

Constipation:

Treatment with HYDRILAXE usually lasts for about 2 weeks. If you need to take HYDRILAXE for longer, please see your doctor. If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS), or if you take medicines that cause constipation your doctor may recommend that you take HYDRILAXE for longer than 2 weeks. If you need to take HYDRILAXE for longer, please see your doctor.

Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with HYDRILAXE can be for up to 3 days.

If you take more HYDRILAXE than you should:

You may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop taking HYDRILAXE and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take HYDRILAXE:

Take the dose as soon as you remember to take it.

If you stop taking or using the HYDRILAXE:

To get the most benefit from HYDRILAXE, always finish the course of treatment recommended by your doctor or pharmacist. This will make sure that your constipation is cleared, otherwise the symptoms you are suffering from may persist. You must contact a doctor

if your symptoms worsen or do not improve after 14 days for chronic constipation, or after 3 days for faecal impaction.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking HYDRILAXE if you:

- Get a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat.

Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood.

Sometimes you may have indigestion, stomach ache or rumbles. You may also feel bloated, suffer from wind, feel sick or vomit, may also experience soreness of the anus (bottom) and may have mild diarrhoea when starting to take HYDRILAXE. These side effects generally get better if you reduce the amount HYDRILAXE you take.

5. How to store HYDRILAXE

Keep this medicine out of the sight and reach of children.

Do not use HYDRILAXE after the expiry date which is stated on the sachet and carton.

Store protected from moisture at a temperature not exceeding 30°C.

Once you have made up HYDRILAXE in water use the reconstituted solution immediately.

Throw away any solution not used within a 6 hour period.

Do not throw away any 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 HYDRILAXE contains

Each sachet of HYDRILAXE contains the following active ingredients: Macrogol 3350 (Polyethylene Glycol) BP 13.125 g, Sodium Chloride BP 350.70 mg, Sodium Bicarbonate BP 178.50 mg, Potassium chloride BP 46.60 mg.

HYDRILAXE also contains Mannitol, Sucralose (Micronized), Orange Flavour (Powdarome Orange 4153), Sunset Yellow FCF.

What HYDRILAXE looks like and contents of the pack

HYDRILAXE is a light orange free flowing powder having pleasant orange flavour odour.

HYDRILAXE is available as 10 Sachets of printed laminate foil, 14 gm each packed in a carton along with an insert.

Marketing Authorisation Holder:

Asterisk Lifesciences (GH Limited,
H. No. AA-2, Manet Vile, Spintex Road,
Accra- Ghana
Phone no: +233-242501878