

APOHEALTH Diarrhoea Relief PLUS

Chewable Tablets

Contains the active ingredient Loperamide hydrochloride and Simethicone

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APOHEALTH Diarrhoea Relief PLUS Chewable Tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

APOHEALTH Diarrhoea Relief PLUS Chewable Tablets are used to treat acute diarrhoea.

APOHEALTH Diarrhoea Relief PLUS Chewable Tablets also relieve the symptoms of too much gas such as abdominal pain, bloating, cramping and flatulence (wind).

Ask your pharmacist or doctor if you have any questions about why this medicine has been prescribed or recommended for you.

How it works

Loperamide make the stools more solid and less frequent.

It does this by normalising the muscle contractions of the intestine.

This allows the bowel time to absorb water and produce a more solid stool.

Simethicone helps the body to get rid of excess gas trapped in the stomach and bowel.

Use in children

This medicine should not be used in children under 12 years.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
- you are constipated, or have to avoid becoming constipated
- you have severe diarrhoea with blood in the stools or fever
- you have inflammation of the lower bowels (for example, ulcerative colitis or pseudomembranous colitis as a result of using antibiotics)
- **You are breastfeeding.**
- **You are hypersensitive to, or have had an allergic reaction to, loperamide, simethicone or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor or pharmacist if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver disease
 - kidney disease

- AIDS (Acquired Immune Deficiency Syndrome)
 - glaucoma (pressure in the eye)
 - bladder problems
 - regularly drink a lot of alcohol.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
 5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with loperamide or simethicone. These include:

- sleeping tablets or medicines to treat anxiety and nervousness
- medicines to treat depression
- medicines that slow down action of the stomach and intestines.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with simethicone or loperamide.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Children:

Do not give this medicine to a child under the age of 12 years.

Adults and children aged 12 years and over:

The usual adult dose is two tablets initially, followed by one tablet after each loose unformed stool as needed.

Do not take more than four tablets in one day.

The tablets should be chewed.

How to take it

This medicine should be chewed, then swallowed. No liquid intake is necessary.

If you forget to take it:

If you forget to take this medicine after an unformed stool, take it when you remember or after your next unformed stool.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you are not sure what to do, check with your doctor or pharmacist.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you overdose on this medicine, you may have any of the following symptoms: sleepiness, nausea, vomiting, constipation, difficulty passing urine, weak breathing, muscle stiffness, stupor, constriction of pupils, abdominal discomfort and distension, and uncoordinated movements.

Children are more sensitive than adults to medicines. An accidental overdose is especially dangerous. Make sure this medicine is kept out of reach of children.

While you are taking this medicine

Things you must do

- If you do not improve after taking this medicine for 48 hours tell your doctor or pharmacist
- Drink plenty of fluids, to avoid dehydration
- Tell your doctor if diarrhoea persists beyond 48 hours
- Tell your doctor if you become pregnant while taking this medicine

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Take more than four tablets in one day
- Give this medicine to anyone else, even if their symptoms seem similar to yours.

- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Tiredness, dizziness or drowsiness can be seen with diarrhoea. Therefore, it is advisable to use caution when driving or operating machinery.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking APOHEALTH Diarrhoea Relief PLUS Chewable Tablets or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- nausea or vomiting
- headache, chills, fever
- constipation dry mouth or bad taste
- dizziness or drowsiness cough

- rash and sweat
- itching
- difficulty passing urine
- tiredness
- abdominal pain/discomfort/distension/
- excessive flatulence indigestion
- rapid heart rate

These side effects are usually mild.

The above list does not represent all side effects that have been reported for this medicine. If you notice side effects not mentioned in this leaflet, please inform your pharmacist or doctor.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

- sudden or severe blisters, itching, skin rash, hives
- flaking or peeling of skin.

Serious side effects are rare.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to this medicine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APOHEALTH Diarrhoea Relief PLUS Chewable Tablets look like

White to off- white, 15.9 mm diameter round bevel edged, slightly mottled, uncoated, chewable tablets

Each pack contains 2, 4, 6, 12 or 18 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 2mg of loperamide hydrochloride and 125 mg of simethicone as the active ingredients.

It also contains the following inactive ingredients:

- magnesium carbonate,
- calcium phosphate,
- glucose,
- povidone,
- silicon dioxide,
- acesulfame potassium, hypromellose,
- xylitol,

- stearic acid,
- and peppermint flavour.

The chewable tablets do not contain gluten.

Australian Registration Numbers

APOHEALTH Diarrhoea Relief PLUS Chewable Tablets
(Blister Pack): AUST R 235981

Sponsor

Apotex Pty Ltd

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Macquarie Park NSW 2113

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