

RENAGEL[®]

Sevelamer hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Renagel. It does not contain all the available information. It does not take the place of talking to your treating physician or a trained health care professional.

All medicines have risks and benefits. Your treating physician has weighed the risks of you taking Renagel against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your treating physician or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Renagel is used for

The name of your medicine is Renagel. It contains the active ingredient called sevelamer hydrochloride.

Renagel is used to treat hyperphosphataemia, a condition caused by too much dietary phosphorus being retained in your body due to a diseased kidney.

Ask your treating physician if you have any questions about why this medicine has been prescribed for you.

How it works

Renagel belongs to a class of medicines that are called ion exchange resins.

Renagel helps to remove excess phosphorus that has built up in your body by binding the phosphorus that is in the food that you eat.

Before you use Renagel

When you must not take it

Do not take Renagel if you have an allergy to:

- any medicine containing sevelamer hydrochloride
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not take Renagel if you have:

- **hypophosphataemia, a condition where you do not have enough phosphorus in your body.**
- **have a bowel obstruction.**

Do not take Renagel if the packaging is torn or shows signs of tampering.

Do not take Renagel after the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date it may have no effect at all, or worse, an unexpected effect.

If you are not sure whether you should start taking this medicine, talk to your treating physician.

Before you start to take it

You must tell your treating physician if you have:

- allergies to any other medicines or substances such as foods, preservatives or dyes.
- swallowing problems
- severe constipation
- problems with movement in your stomach and bowel
- active inflammation of the bowel
- undergone major surgery on your stomach or bowel
- you have or have had any other medical conditions, including a bowel obstruction or hypophosphatemia
- if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby

If you have not told your treating physician about any of the above, tell them before you take Renagel.

Taking other medicines

Tell your treating physician if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Renagel or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your treating physician will advise you.

The effects of medicines such as cyclosporin, mycophenolate mofetil and tacrolimus (medicines used to suppress the immune system) may be reduced by Renagel. Your doctor will advise you if you are taking these medicines.

Renagel should not be taken at the same time as ciprofloxacin (an antibiotic).

How to take Renagel

How much to take

Your treating physician may initially prescribe 1 - 2 Renagel 800 mg tablets three times a day with your meals. Your doctor may adjust your dosage during treatment depending on your blood test results. The average daily dose of Renagel is 3 Renagel 800mg tablets per meal

Follow all directions given to you by your treating physician and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your treating physician or pharmacist for help.

How to take it

Swallow Renagel tablets whole with a glass of water. Do not chew them. If you are having difficulty swallowing Renagel tablets, speak to your healthcare professional.

When the contents of Renagel come into contact with water they expand making them hard to swallow, therefore do NOT crush, chew or break the tablets into pieces before you take them.

How long to take it

Renagel helps lower your dietary phosphate. It does not cure your

condition. Therefore, you must continue to take it as directed by your treating physician if you expect to lower your phosphate level and keep it down. You may have to take phosphate-lowering medicine for the rest of your life. If you stop taking Renagel, your phosphate levels may rise again. It is important to keep taking your medicine even if you feel well.

Do not stop taking Renagel.

Your treating physician may need to change the dose of your other medicines if you stop Renagel, so you should only stop when your treating physician tells you to.

If you forget to take it

If you miss a dose, do not take an extra dose to make up for the one you missed. Just go back to taking your tablets as you would normally.

It is important to try to take Renagel as prescribed by your treating physician.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your treating physician or Poisons Information Centre [Australia telephone 13 11 26; in New Zealand telephone 0800 POISON or 0800 764 766], or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Renagel. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places handy

While you are using Renagel

Things you must do

If you become pregnant while you are taking Renagel tell your treating physician.

If you are about to be started on any new medicine tell your treating physician and pharmacist that you are taking Renagel.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor will check your progress and monitor your phosphorus levels from time to time. This helps to ensure you are getting the right dose of Renagel.

Things you must not do

Do not give Renagel to anyone else, even if they have the same condition as you.

Do not use Renagel to treat any other complaints unless your treating physician tells you to.

Do not stop taking your medicine or lower the dosage without checking with your treating physician.

Side effects

Check with your treating physician as soon as possible if you do not feel well or have any problems while taking Renagel, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Renagel can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your treating physician or pharmacist any questions you may have.

Tell your treating physician if you notice any of the following and they worry you:

- vomiting
- nausea
- constipation
- diarrhoea
- flatulence
- indigestion
- abdominal pain

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following symptoms:

- rash, itching or hives on the skin
- severe constipation

If any of the following happen, tell your doctor immediately or go to the Accident and Emergency at your nearest hospital:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Other side effects not listed above may occur in some patients. Tell your treating physician if you notice anything making you feel unwell when you are taking, or soon after you have finished taking, Renagel.

After using Renagel

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep Renagel in a cool dry place where the temperature stays below 25°C with the lid tightly closed. Do not put Renagel in the refrigerator. Do not store it or any other medicine in the bathroom or near a

sink. Do not leave it in the car or on the window sills.

Heat and dampness can destroy some medicines.

Keep it 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 treating physician tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Renagel is available as:

Renagel 400mg* tablets are off-white, oval shaped tablets with "Renagel 400" printed on one side.

AUSTR 101550

Renagel 800mg tablets are off-white, oval shaped tablets with "Renagel 800" printed on one side.

AUSTR 101553

* Presentations currently not marketed

Ingredients

Active ingredient: sevelamer hydrochloride

Other ingredients: hypromellose, diacetylated monoglycerides, colloidal anhydrous silica and stearic acid

Renagel does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes

Manufacturer

In Australia this product is registered by:

Genzyme Australasia Pty Ltd
Building D

12-24 Talavera Rd

Macquarie Park NSW 2113

Toll Free Number (medical information): 1800 818 806

In New Zealand this product is distributed by:

sanofi-aventis new zealand limited

Level 8, James & Wells Tower

56 Cawley Street

Ellerslie

Auckland

New Zealand

Toll Free Number (medical information): 0800 283 684

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Further information is available via the App below.



Login code to access Renagel App: kidney