

Renagel®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Renagel?

Renagel contains the active ingredient 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.

For more information, see Section [1. Why am I using Renagel?](#) in the full CMI.

2. What should I know before I use Renagel?

Do not use if you have ever had an allergic reaction to Renagel or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Renagel?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Renagel and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Renagel?

- Your treating doctor will tell you how many tablets to take each day. The initial dose is usually 1 - 2 tablets three times a day with meals. Your doctor may adjust your dosage depending on your blood test results.
- Renagel tablets should be swallowed whole with a glass of water during mealtimes. Do not chew, crush, or break the tablets into pieces before taking them.

More instructions can be found in Section [4. How do I use Renagel?](#) in the full CMI.

5. What should I know while using Renagel?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Renagel.• Keep your doctor's appointments so your progress can be checked. Your doctor will check your progress and monitor your phosphate levels from time to time.
Things you should not do	<ul style="list-style-type: none">• Give Renagel to anyone else, even if they have the same condition as you.• Use Renagel to treat any other complaints unless your treating doctor tells you to.• Stop taking Renagel or change the dosage without checking with your treating doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful while you drive or use any machines or tools until

	you know how Renagel affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Keep your tablets in the bottle until it is time to take them. • 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, in the bathroom, near a sink, in the car or on windowsills.

For more information, see Section [5. What should I know while using Renagel?](#) in the full CMI.

6. Are there any side effects?

Common side effects: vomiting, nausea, constipation, heartburn, diarrhoea, abdominal pain, flatulence, headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RENAGEL®

Active ingredient: *Sevelamer hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Renagel. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Renagel.**

Where to find information in this leaflet:

- [1. Why am I using Renagel?](#)
- [2. What should I know before I use Renagel?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Renagel?](#)
- [5. What should I know while using Renagel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Renagel?

Renagel contains the active ingredient sevelamer hydrochloride. 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.

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

2. What should I know before I use Renagel?

Warnings

Do not use Renagel if:

- you are allergic to sevelamer hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you have hypophosphatemia, a condition where you do not have enough phosphorus in your body.
- you have a bowel obstruction.
- the packaging is torn or shows sign of tampering.
- the expiry date (EXP) printed on the pack has passed.

Check with your doctor 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.
- any other medical conditions.
- take any medicines for any other conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements 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 doctor will advise you.

Medicines that may be affected by Renagel include:

- ciclosporin

- mycophenolate mofetil
- tacrolimus
- ciprofloxacin

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Renagel.

4. How do I use Renagel?

How much to take?

- Follow the instructions provided by your treating doctor and pharmacist carefully. These directions may differ from the information contained within this leaflet.
- Your treating doctor may initially prescribe 1 - 2 Renagel 800mg tablets three times a day with meals. Your doctor may adjust your dosage during treatment depending on your blood test results.

When to take Renagel?

- Renagel tablets should be taken with meals.
- The tablets should be swallowed whole with a glass of water. Do not chew, crush, or break the tablets into pieces before taking them.
- When the contents of Renagel tablets are exposed to water, they expand making them hard to swallow.
- If you are having difficulty swallowing Renagel tablets, speak to your healthcare professional.

How long to take Renagel for?

- Renagel helps lower your body's retention of dietary phosphate. It does not cure your condition. Therefore, you must continue to take it for as long as your treating doctor directs you to.
- You may have to take Renagel for the rest of your life. If you stop taking Renagel, your phosphate levels may rise again. It is important to keep taking Renagel even if you feel well.

If you forget to use Renagel

Renagel should be taken at the same times each day. If you miss your dose at the usual time, do not take an extra dose to make up for the one you missed.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

If you take too much Renagel

If you think that you have taken too much Renagel, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Renagel?

Things you must do

Call your doctor straight away if you:

- become pregnant while you are taking Renagel.
- start to feel unwell or have any problems while you are taking Renagel, even if you do not think the problems are related to Renagel or are not listed in this leaflet.

Remind any doctor, dentist, or pharmacist you visit that you are using Renagel.

Things you must not do:

- give Renagel to anyone else, even if they have the same condition as you.
- use Renagel to treat any other complaints unless your treating doctor tells you to.
- stop taking Renagel or change the dosage without checking with your treating doctor.

Things you should do:

- keep your doctor's appointments so your progress can be checked. Your doctor will check your progress and monitor your phosphate levels from time to time. This helps to ensure you are getting the correct dose of Renagel.

Driving or using machines

Be careful while you drive or use any machines or tools until you know how Renagel affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● Vomiting● Nausea● Constipation● Dyspepsia (heartburn)● Diarrhoea● Abdominal pain● Flatulence (passing wind)● Headache	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not normally require treatment to be interrupted.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Rash, itching or hives (red raised circular bumps) on the skin ● Severe constipation (prolonged absence of bowel movement, major bloating and/or severe abdominal pain) ● Vomiting blood or material that looks like coffee grounds ● Bleeding from the rectum, black sticky bowel movements, bloody diarrhoea ● Fever or high temperature 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
<p>Allergy-related symptoms:</p>	<p>What to do</p>
<ul style="list-style-type: none"> ● Shortness of breath ● Wheezing or difficulty breathing ● Swelling of the face, lips, tongue or other parts of the body 	<p>Stop taking Renagel and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
	notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Renagel contains

Active ingredient (main ingredient)	Each tablet contains 800mg of sevelamer hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Colloidal anhydrous silica• Stearic acid• OPADRY complete film coating system 06A29064 Clear
Potential allergens	Renagel does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Renagel looks like

Renagel 800mg tablets are oval off-white film coated tablets with "RG800" engraved on one side and blank on the other side. (AUST R 101553).

Who distributes Renagel

Distributed by:
sanofi-aventis australia pty ltd

12-24 Talavera Road
Macquarie Park NSW 2113
Freecall: 1800 818 806
Email: medinfo.australia@sanofi.com

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