

SEVELAMER LUPIN

(sevelamer carbonate) film-coated tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sevelamer Lupin.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sevelamer Lupin against the benefits this medicine is expected to have for you.

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

Keep this leaflet.

You may need to read it again.

What Sevelamer Lupin is used for

Sevelamer Lupin contains the active substance sevelamer carbonate and is used to treat hyperphosphatemia, a condition caused by too much dietary phosphorus being retained in your body due to a diseased kidney.

Increased levels of serum phosphorus can lead to hard deposits in your body called calcification. These deposits can stiffen your blood vessels and make it harder for blood to be pumped around the body.

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

Your doctor, however, may have prescribed Sevelamer Lupin for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

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

Before you take Sevelamer Lupin

When you must not take it

Do not take Sevelamer Lupin if you have an allergy to:

- any medicine containing sevelamer carbonate (the active ingredient);
- any of the ingredients listed at the end of this leaflet;
- any other similar medicine, such as sevelamer hydrochloride.

Symptoms that may indicate an allergic reaction include:

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

Tell your doctor if you are experiencing any of the above symptoms.

Do not take Sevelamer Lupin if you:

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

Sevelamer Lupin should not be used after the expiry date (EXP) printed on the pack.

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

Sevelamer Lupin should not be used if the packaging is torn or shows signs of tampering.

Do not give Sevelamer Lupin to children.

The safety and efficacy of Sevelamer Lupin in children under the age of 18 years has not been established.

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

Before you start to take it

Tell your doctor or pharmacist 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;
- thyroid problems;
- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.

Tell your doctor about any of the above before you take Sevelamer Lupin.

Additional Information

Due to either your kidney condition or your dialysis treatment you may:

- Develop low or high levels of calcium in your blood. Since Sevelamer Lupin does not contain calcium your doctor might prescribe additional calcium tablets.
- Have a low amount of vitamin D in your blood. Therefore, your doctor may monitor the levels of vitamin D in your blood and prescribe additional vitamin D as necessary. If you do not take multivitamin supplements you may also develop low levels of vitamins A, E, K and folic acid in your blood and therefore your doctor may monitor these levels and prescribe supplemental vitamins as necessary.
- Develop peritonitis (infection of your abdominal fluid) associated with your peritoneal dialysis. This risk can be reduced by careful adherence to sterile techniques during bag changes. You should tell your doctor immediately if you experience any new signs or symptoms of abdominal distress, abdominal swelling, abdominal tenderness, constipation, fever, chills, nausea or vomiting.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines (including vaccinations), medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Sevelamer Lupin or may affect how well Sevelamer Lupin works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor 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 Sevelamer Lupin. Your doctor will advise you if you are taking these medicines.

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

Thyroid hormone deficiency may uncommonly be observed in certain people taking levothyroxine (used to treat low thyroid hormone levels) and Sevelamer Lupin. Therefore, your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.

If you are taking medicines for heart rhythm problems or for epilepsy, you should consult your doctor before taking Sevelamer Lupin.

How to take Sevelamer Lupin

How much to take

The recommended starting dose of Sevelamer Lupin is 2.4 g to 4.8 g per day to be taken over 3 meals.

For tablets, this means one to two 800 mg tablets with each meal three times a day.

The dose will depend on your serum phosphorus level.

Follow all directions given to you by your doctor or pharmacist carefully.

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

How to take it

Swallow Sevelamer Lupin tablets whole with a glass of water. Do not crush, chew or break into pieces.

If you are having difficulty swallowing Sevelamer Lupin tablets, speak to your doctor.

How long to take it

Sevelamer Lupin helps lower your dietary phosphate. It does not cure your condition. Therefore, you must continue to take it as directed by your doctor if you expect to lower your phosphate level and keep it down.

You may have to take phosphate-lowering medicines for the rest of your life. If you stop taking Sevelamer Lupin, your phosphate levels may rise again. It is important to keep taking your medicines even if you feel well.

Do not stop taking Sevelamer Lupin. Your doctor may need to change the dose of your other medicines if you stop taking Sevelamer Lupin, 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. Take the next dose at the usual time with your meal.

It is important to take Sevelamer Lupin as prescribed by your doctor.

If you take too much (overdose)

Immediately telephone your treating physicians 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 Sevelamer Lupin.

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 taking Sevelamer Lupin

Things you must do

If you become pregnant while you are taking Sevelamer Lupin, tell your doctor.

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Sevelamer Lupin.

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 Sevelamer Lupin.

Things you must not do

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

Do not use Sevelamer Lupin to treat any other complaints unless your doctor tells you to.

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

Side effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are taking Sevelamer Lupin.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If any of the following happen after you have taken Sevelamer

Lupin tell your doctor or pharmacist:

- 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 in 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 doctor if you notice anything making you feel unwell when you are taking, or soon after you have finished taking Sevelamer Lupin.

After taking Sevelamer Lupin

Storage

Keep Sevelamer Lupin in a cool dry place where the temperature stays below 25°C.

Do not put Sevelamer Lupin in the refrigerator.

Do not put it in the bathroom or near the sink.

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

Heat and dampness can destroy some medicines.

Keep Sevelamer Lupin where young children cannot reach it. A locked cupboard at least one and a

half meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Sevelamer Lupin or your Sevelamer Lupin tablets have passed their expiry date, ask your pharmacist what to do with any tablet that is left over.

Product description

What it looks like

Sevelamer Lupin 800 mg is available as tablets.

Sevelamer Lupin 800 mg tablets are white to off-white, oval, film-coated tablets imprinted with 'R789' on one side and are plain on the other side.

Ingredients

Active ingredient:

- sevelamer carbonate

Other ingredients:

- mannitol;
- crospovidone;
- zinc stearate;
- hypromellose;
- silicon dioxide;
- polyvinyl alcohol;
- purified talc;
- lecithin;
- xanthan gum;
- purified water.

Australian Registration Numbers

Sevelamer Lupin 800 mg tablet:
AUST R 286651

Distributor

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