

<i>Applicant/PHCR:</i>	Macleods Pharmaceuticals SA (Pty) Ltd
<i>Product Name:</i>	Sevelamer Carbonate 800 mg, film-coated tablets
<i>Active Ingredient:</i>	Sevelamer Carbonate
<i>Dosage Form:</i>	Film-coated tablets
<i>Date:</i>	26 June 2026

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SCHEDULING STATUS: S4

MAKOSEV 800 (film coated tablet)

Sevelamer Carbonate

Sugar free

Read all of this leaflet carefully before you start taking MAKOSEV 800

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **MAKOSEV 800** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **MAKOSEV 800** is and what it is used for
2. What you need to know before you take **MAKOSEV 800**
3. How to take **MAKOSEV 800**
4. Possible side effects
5. How to store **MAKOSEV 800**
6. Contents of the pack and other information

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1. What MAKOSEV 800 is and what it is used for

MAKOSEV 800 contains sevelamer Carbonate.

MAKOSEV 800 binds phosphate from food in the digestive tract and so reduces serum phosphorus levels in the blood.

MAKOSEV 800 is used to control hyperphosphataemia (high blood phosphate levels) in:

- adult patients on dialysis (a blood clearance technique). It can be used in patients undergoing haemodialysis (using a blood filtration machine) or peritoneal dialysis (where fluid is pumped into the abdomen and an internal body membrane filters the blood);
- patients with chronic (long-term) kidney disease who are not on dialysis and have a serum (blood) phosphorus level equal to or above 1,78 mmol/l.

2. What you need to know before you take MAKOSEV 800

Do not take MAKOSEV 800:

- If you are allergic to sevelamer or any of the other ingredients of this medicine, listed in section 6.
- If you have low phosphate levels in your blood.
- If you have bowel obstruction.

Warnings and precautions

Talk to your doctor before taking **MAKOSEV 800** if you have

Swallowing problems

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Problems with motility (movement) in your stomach or bowel.

Frequently being sick

Have undergone major surgery on your stomach or bowel.

Take special care with MAKOSEV 800

If you experience severe abdominal pain, stomach or intestine disorders, or blood in the stool (gastrointestinal bleeding). These symptoms can be due to serious inflammatory bowel disease caused by sevelamer crystals deposit in your bowel. Contact your doctor who will decide on continuing the treatment or not.

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

- develop low or high levels of calcium in your blood. Since **MAKOSEV 800** 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.
- have disturbed level of bicarbonate in your blood and increased acidity in the blood and other body tissue. Your doctor should monitor the level of bicarbonate in your blood.

Special note for patients on peritoneal dialysis

You may 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 pain, abdominal tenderness, or abdominal rigidity,

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constipation, fever, chills, nausea or vomiting.

Other medicines and MAKOSEV 800

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ciprofloxacin as **MAKOSEV 800** should not be taken at the same time as ciprofloxacin (an antibiotic).
- medicines for heart rhythm problems or for epilepsy.
- medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (medicines used to suppress the immune system) the effects of which may be reduced by **MAKOSEV 800**.
- Levothyroxine as thyroid hormone deficiency may uncommonly be observed in certain people taking levothyroxine (used to treat low thyroid hormone levels) and **MAKOSEV 800**. Therefore your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.
- Medicines treating heartburn and reflux from your stomach or oesophagus, such as omeprazole, pantoprazole, or lansoprazole, known as “proton pump inhibitors”, may reduce the efficacy of **MAKOSEV 800**. Your doctor may monitor the phosphate level in your blood.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **MAKOSEV 800**.

You should not take this medicine if you are pregnant.

Do not take **MAKOSEV 800** while breastfeeding.

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Driving and using machines

MAKOSEV 800 is not expected to affect your ability to drive a vehicle or operate machinery. Take care until you know how **MAKOSEV 800** affects you.

It is not always possible to predict to what extent **MAKOSEV 800** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **MAKOSEV 800** affects them.

3. How to take MAKOSEV 800

Do not share medicines prescribed for you with any other person.

Always take **MAKOSEV 800** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet of **MAKOSEV 800** three times a day with meals.

The tablets should be swallowed intact and should not be crushed or broken into pieces prior to administration.

Your doctor will check the levels of phosphorus in your blood periodically and they may adjust the dose of **MAKOSEV 800** when necessary to reach an adequate phosphate level.

If you have the impression that the effect of **MAKOSEV 800** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MAKOSEV 800 than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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If you forget to take MAKOSEV 800

It is important to take your **MAKOSEV 800** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking MAKOSEV 800

If **MAKOSEV 800** is stopped earlier than your doctor has prescribed, your symptoms may return or worsen. Always take **MAKOSEV 800** for as long as your doctor has prescribed.

4. Possible side effects

MAKOSEV 800 can have side effects.

Not all side effects reported for **MAKOSEV 800** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MAKOSEV 800**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **MAKOSEV 800** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **MAKOSEV 800**. You may need urgent medical attention or hospitalisation.

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

- severe pain in your stomach area with blood in your stools or vomit, which may be signs of a perforation in your intestinal wall
- constipation, which may be an early sign of a blockage in your intestine (see section 2)
- serious inflammation of the large bowel (symptoms include: severe stomach pain, stomach or intestinal disorders, or blood in your stools [gastrointestinal bleeding]).

Tell your doctor if you notice any of the following:

Frequently occurring:

- Vomiting,
- Upper abdominal pain
- Nausea
- Diarrhoea
- Stomach ache
- Indigestion
- Flatulence

Frequency not known:

- Itching
- Rash
- slow intestine motility (movement)/blockages in the intestine and perforation in the intestine (see section 2).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or

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pharmacist.

Should your general health worsen or if you experience any untoward effects while taking **MAKOSEV 800**, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **MAKOSEV 800**.

5. How to store MAKOSEV 800

Store at or below 25 °C. Protect from moisture.

KEEP OUT OF REACH OF CHILDREN.

Store in the original package / container.

Keep the bottle tightly closed.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What MAKOSEV 800 contains

The active ingredient is sevelamer Carbonate.

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Core tablet ingredients are:

- Microcrystalline cellulose
- Hydroxypropyl Cellulose
- Colloidal silicon dioxide
- Zinc Stearate

Coating ingredients contains:

- Hypromellose-15
- Hypromellose-5
- Di-Acetylated Monoglycerides

Imprinting ingredients contains:

- Black Iron Oxide
- Propylene Glycol

What MAKOSEV 800 looks like and contents of the pack

MAKOSEV 800: White to off white, oval shaped, biconvex, film coated tablets imprinted with "L 28" on one side and plain on other side.

Contents of the pack:

Tablets are packed in white, round, round 500 cc HDPE bottle closed with a white child resistant closure with pulp and heat seal white printed liner.

Pack size: 30, 180, 270's

Not all pack sizes may be marketed.

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7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Ground Floor, Block 1,

Bassonia Estate Office Park (East),

1 Cussonia Drive,

Bassonia Rock Ext 12

Alberton

Gauteng

This leaflet was last revised in

09 June 2026

Registration numbers

MAKOSEV 800: 59/32.16/0217

Access to the corresponding Professional Information

The corresponding professional information can be accessed at

<https://www.macleodssaproducts.co.za> or email macleodsrso@macleodspharma.com or contact

011 682 1169.

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