HEALOL Sevelamer Carbonate 800mg Film Coated Tablets

Sevelamer Carbonate 800mg

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What HEALOL SEVELAMER is used for

HEALOL SEVELAMER is used for patients who have kidneys that do not work properly are not able to control the level of serum phosphorus in their blood. The amount of phosphate then rises (your doctor will call this hyperphosphataemia). 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. Increased serum phosphorus can also lead to itchy skin, red eyes, bone pain and fractures.

How HEALOL SEVELAMER works

HEALOL SEVELAMER contains sevelamer carbonate as the active ingredient. It binds phosphate from food in the digestive tract and so reduces serum phosphorus levels in the blood.

Before you use HEALOL SEVELAMER

When you must not use it

Do not take HEALOL SEVELAMER if:

• You are allergic (hypersensitive) to sevelamer carbonate, sevelamer hydrochloride, or to any of the other ingredients of this medicine (listed in Section 8 below).

-Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

• You have bowel obstruction.

Before you start to use it

Check with your doctor before taking HEALOL SEVELAMER if:

• You have swallowing problems

• You have problems related with motility (movement) in your stomach and bowel

• You are being sick frequently

• You have active inflammation of the bowel

• You have undergone major surgery on your stomach or bowel

• You have severe constipation.

Additional treatments:

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

- develop low or high levels of calcium in your blood. Since HEALOL SEVELAMER 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

If you are taking medicines for heart rhythm problems or for epilepsy, you should consult your doctor when taking HEALOL SEVELAMER.

The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (medicines used to suppress the immune system) may be reduced by HEALOL SEVELAMER.

Your doctor will advise you if you are taking these medicines. Thyroid hormone deficiency may uncommonly be observed in certain people taking levothyroxine (used to treat low thyroid hormone levels) and HEALOL SEVELAMER. Therefore your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.

How to use HEALOL SEVELAMER

Always take HEALOL SEVELAMER exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

• Swallow your tablets orally in whole with plenty of water.

• Do not crush, chew or break into pieces.

• You must take HEALOL SEVELAMER with meals.

How much to use

Your doctor will prescribe HEALOL SEVELAMER to you based on your serum phosphorus level.

The recommended starting dose of HEALOL SEVELAMERs for adults and the elderly (> 65 years) is **one to two tablets of 800mg with each meal, 3 times a day.**

In some cases where HEALOL SEVELAMER should be taken at the same time as another medicine. Your doctor may advise you to take this medicine 1 hour before or 3 hours after HEALOL SEVELAMER intake, or they may consider monitoring the blood levels of that medicine.

HEALOL SEVELAMER is not recommended for use in children and adolescents below 18 years of age.

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When to use it
Take HEALOL SEVELAMER at about the same time each day unless your doctor tells you otherwise.

How long to use it
Continue taking your medicine for as long as your doctor tells you.

If you forget to use it
- If you forget to take your tablet, leave out that dose completely and take the next tablet at the usual time.
- Do not take a double dose to make up for a forgotten tablet.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you use too much (overdose)
There are no reported overdoses in patients. In the event of a possible overdose you should contact your doctor immediately. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it
Things you must do
Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine if:
• You are pregnant, think you may be pregnant or are planning to have a baby. It is unknown whether HEALOL SEVELAMER has any effect on unborn babies.
• You wish to breast-feed your baby. It is unknown whether HEALOL SEVELAMER may pass through breast milk and affect your baby.

Things you must not do
• Do not give this medicine to anyone else, even if they have the same condition as you.
• Do not use this medicine to treat any other complaints unless your doctor tells you to.
• Do not stop taking HEALOL SEVELAMER, or change the dosage, without checking with your doctor.

Things to be careful of
Side effects
Gastrointestinal Adverse Events
Cases of dysphagia and esophageal tablet retention have been reported in association with use of the tablet formulation of sevelamer, some requiring hospitalization and intervention. Consider using sevelamer suspension in patients with a history of swallowing disorders.

Cases of bowel obstruction, bleeding gastrointestinal ulcers, colitis, ulceration, necrosis, and perforation have also been reported with sevelamer use. Inflammatory disorders may resolve upon HEALOL SEVELAMER discontinuation.
Treatment with HEALOL SEVELAMER should be re-evaluated in patients who develop severe gastrointestinal symptoms.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI).

Storage and Disposal of HEALOL SEVELAMER
If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage
- Keep this medicine out of sight and reach of children.
- Do not use HEALOL SEVELAMER after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store below 30°C. Keep the bottle tightly closed in order to protect from moisture.

Disposal
Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
What it looks like
HEALOL SEVELAMER tablets, for oral use are 800 mg white or off-white oval film coated tablets, debossed with "XH" on one side and "800" on the other side.

The tablets are packed in high density polyethylene bottles with a polypropylene cap and an induction seal.
Pack size: 1 x 180 tablets per bottle

Ingredients:
- The active substance is sevelamer carbonate. Each HEALOL SEVELAMER film-coated tablet contains 800 mg of sevelamer carbonate.
- The inactive ingredients are Mannitol, Crospovidone, Hydroxypropyl cellulose, Colloidal silicon dioxide, Talc, Glyceryl dibehenate and Opadry® 06A590025-CN.

MAL Numbers:
MAL26076039AZ

Manufacturer and Product Registration Holder
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Product Registration Holder
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