

# Sevela Film-Coated Tablet 800mg

*Sevelamer Carbonate 800mg*



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## What Sevela is used for

The name of your medicine is Sevela Tablet 800mg (called "Sevela" in this leaflet). Sevela contains a medicine called Sevelamer Carbonate. Sevela is a phosphate binder to be used for the control of serum phosphorus in adults receiving haemodialysis or peritoneal dialysis, or with chronic kidney disease not on dialysis with serum phosphorus  $\geq 1.78$  mmol/l. Sevela should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D3 or one of its analogues to control the development of renal bone disease.

## How Sevela works

Sevela is a prescription medication containing Sevelamer carbonate. It binds phosphate from food in the digestive tract and so reduces serum phosphorus levels in the bloods.

## Before you use Sevela

### When you must not use it:

Do not use this product if you have bowel obstruction or you are allergic to sevelamer carbonate, sevelamer hydrochloride, or any other ingredients in this medication. (Please refer to product description)

## Pregnancy and lactation

Do not take Sevela if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Sevela if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

### Before you start use it:

Before taking Sevela your doctor needs to know if you have any other medical condition that you may have, including swallowing problems, problems with motility (movement) in your stomach and bowel, being sick frequently, active inflammation of the bowel, have undergone major surgery on your stomach or bowel.

### Taking other medicines:

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

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

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

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

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

## How to use Sevela

### How much to use:

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The initial starting dose of Sevela is one to two tablets of 800mg three times daily with each meal.

The tablet is for oral use.

The tablets should be swallowed intact and should not be crushed, chewed, or broken into pieces prior to administration. Sevela should be taken with food and not on an empty stomach.

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

### When to use it:

Use as directed by your doctor or pharmacist.

### How long to use it:

Continue taking Sevela-for as long as your doctor recommends.

### If you forget to use it:

Consult your doctor or pharmacist on what you should do if you forget to use it. If you have missed one dose, this dose should be omitted and the next dose should be taken at the usual time with a meal. Do not take double dose to make up for a forgotten dose.

### If you use too much (overdose):

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. 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:

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Sevela-

Tell your doctor immediately if you become pregnant while taking this medication.

**Things you must not do:**

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

**Things to be careful of:**

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, constipation, fever, chills, nausea or vomiting.

You should expect to be monitored more carefully for problems with low levels of vitamins A, D, E, K and folic acid.

**Driving and using machines:**

No studies on the effects on the ability to drive and use machines has been performed. If you are affected, do not drive and do not use any tools or machines.

**Side effects**

Like all medicines, Sevela can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

In long-term studies with sevelamer hydrochloride, which contains the same active ingredient as sevelamer carbonate, the most common adverse events included: vomiting (22%), nausea (20%), diarrhea (19%), dyspepsia (16%), abdominal pain (9%), flatulence (8%) and constipation (8%).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→Reporting Side Effects to

Medicines (ConSERF) or Vaccines (AEFI)]

**Storage and Disposal of Sevela**

- Storage

Keep out of the reach and sight of children.

Store below 30°C and protect from light.

- 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**

Off-white to white oval shaped film-coated tablet, "CH86" on single side.

**Ingredients**

**Active ingredient:**

Sevelamer Carbonate

**Inactive ingredients:**

Microcrystalline Cellulose, Sodium Chloride, Magnesium Stearate, Silicon Dioxide, Purified Water, Stearic Acid, HPMC and PEG6000.

MAL number:

MAL22016008ACZ

**Manufacturer**

Chen Ho Pharmaceutical Co., Ltd.  
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**Product Registration Holder**

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**Date of revision**

09/06/2026

**Serial Number:**

NPRA (R2) 20/041