

CAESEVA 800MG FILM COATED TABLET

Sevelamer Carbonate (800mg)

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What CAESEVA is used for

CAESEVA 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 CAESEVA works

CAESEVA 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 CAESEVA

- When you must not use it

Do not use CAESEVA if:

- you are allergic to the sevelamer carbonate 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 low levels of phosphate in your blood (your doctor will check this for you).
- you have bowel obstruction.

- Before you start to use it

You must tell your doctor if:

- you have swallowing problems
- you have problems 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 serious inflammatory bowel disease

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 CAESEVA 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.

The safety and efficacy in children (below the age of 6 years) have not been studied. Therefore, this medicine is not recommended for use in

children below the age of 6 years.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. The potential risk of CAESEVA during human pregnancy is unknown. Talk to your doctor who will decide if you can continue the treatment with CAESEVA.

It is unknown whether CAESEVA is excreted in breast milk and may affect your baby. Talk to your doctor who will decide if you can breastfeed your baby or not, and if it is necessary to stop CAESEVA treatment.

CAESEVA contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

- Taking other medicines

Tell your doctor if you are taking or have recently taken or might take any other medicines.

- CAESEVA 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 CAESEVA
- The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (medicines used to suppress the immune system) may be reduced by CAESEVA. 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 CAESEVA. 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 CAESEVA. Your doctor may monitor the phosphate level in your blood.

Your doctor will check for interactions between CAESEVA and other medicines on a regular basis.

In some cases where CAESEVA 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 CAESEVA intake. Your doctor may also consider monitoring the levels of that medicine in your blood.

How to use CAESEVA

Always take CAESEVA 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 CAESEVA with meals.

- How much to use

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

The recommended starting dose of CAESEVA tablets 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 CAESEVA 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 CAESEVA intake, or they may consider monitoring the blood levels of that medicine.

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

- When to use it

Take CAESEVA after your meal or with food. The tablets must be swallowed whole. Do not crush, chew or break into pieces.

- How long to use it

You must take CAESEVA as prescribed by your doctor. They will base the dose on your serum phosphorus level.

- 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 a double dose to make up for a forgotten dose.

- If you use too much (overdose)

In the event of a possible overdose you should contact your doctor immediately.

While you using it

- Things you must do

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

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, constipation, fever, chills, nausea or vomiting.

- Things you must not do

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

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

- Things to be careful of

Be careful driving or operating machinery until you know how CAESEVA affects you.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Constipation is a very common side effect (may affect more than 1 in 10 people). It can be an early symptom of a blockage in your intestine. In case of constipation, please inform your doctor or pharmacist.

Some side effects could be serious. If you get any of the following side effects, seek immediate medical attention:

- Allergic reaction (signs including rash, hives, swelling, trouble breathing). This is a very rare side effect (may affect up to 1 in 10,000 people).
- Blockage in the intestine (signs include: severe bloating; abdominal pain, swelling or cramps; severe constipation) has been reported. Frequency is not

known (frequency cannot be estimated from the available data).

- Rupture in the intestinal wall (signs include: severe stomach pain, chills, fever, nausea, vomiting, or a tender abdomen) has been reported. Frequency is not known.
- Intestinal bleeding, inflammation of the large bowel and crystal deposit in the intestine have been reported. Frequency not known.

Other side effects have been reported in patients taking CAESEVA:

Very common (may affect more than 1 in 10 people):

- Vomiting
- Upper abdominal pain
- Nausea

Common (may affect up to 1 in 10 people):

- Diarrhoea
- Stomach ache
- Indigestion
- Flatulence

Not known (frequency cannot be estimated from the available data):

Cases of itching, rash, slow intestine motility (movement)

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 [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of CAESEVA

- Storage
 - Keep this medicine out of the sight and reach of children.
 - Do not use this medicine after the expiry date stated on the bottle and carton after the letters "EXP". The expiry date refers to the last day of that month.

- Keep the bottle container tightly closed in order to protect from moisture. This medicinal product does not require any special storage conditions.
- Store below 30°C

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

CAESEVA 800MG FILM-COATED TABLET is oval, white to off-white film-coated tablets without scoring line. The tablets are debossed with 'SVL' on one side.

- Ingredients

Active Ingredient:

- Sevelamer Carbonate

Inactive Ingredients:

Tablet core:

- Lactose monohydrate
- Silica, colloidal anhydrous
- Zinc stearate

Film-coating:

- Opadry® 06A29148
- Purified Water

- MAL numbers

CAESEVA 800MG FILM-COATED TABLET
MAL22116017AZ

Manufacturer

Synthon Hispania S.L
C/Castello, 1, 08830 Sant Boi de Llobregat, Barcelona, SPAIN

Product Registration Holder

DUOPHARMA (M) SDN. BHD.

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