

VELSONE 800MG FILM COATED TABLETS

Sevelamer Carbonate 800mg

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What Velsone is used for

Velsone is used for patients who have kidneys that do not work properly where they 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 Velsone works

Velsone 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 Velsone

– When you must not use it

Do not take Velsone if:

- You are allergic (hypersensitive) to 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

Check with your doctor before taking Velsone 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 Velsone 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.

Velsone 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 Velsone.

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

Thyroid hormone deficiency may uncommonly be observed in certain people taking

levothyroxine (used to treat low thyroid hormone levels) and Velsone. Therefore, your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.

How to use Velsone

Always take Velsone 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 Velsone with meals.

– How much to use

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

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

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

– When to use it

Take Velsone 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.

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– *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 Velsone has any effect on unborn babies.
- You wish to breast-feed your baby. It is unknown whether Velsone 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 Velsone, or change the dosage, without checking with your doctor.

– *Things to be careful of*

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, Velsone can cause side effects, although not everyone gets them.

Do not be alarmed by this list of possible side effects.

You may not experience any of them. Tell your doctor immediately.

Very common side effects

- Vomiting
- Constipation

- Upper abdominal pain
- Nausea

Common side effects

- Diarrhoea
- Abdominal pain
- Indigestion
- Flatulence

Cases of hypersensitivity, itching, rash, slow intestine motility (movement)/ blockages in the intestine, and perforation in the intestine wall have been reported.

Since constipation may be an early symptom of a blockage in your intestine, please inform your doctor or pharmacist.

Other side effects not listed above may occur in some people.

Visit your doctor or pharmacist immediately if you experience any side effects listed or not listed above after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Velsone

– *Storage*

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of that month.

Store below 30°C. 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*

Off white, oval shaped film-coated tablet, debossed with 'C 22' on one side and plain on the other side.

The tablets are packed in high density polyethylene bottles with a polypropylene cap of 180's packed in the outer carton.

– *Ingredients*

– Active ingredient

The active substance of Velsone is Sevelamer Carbonate 800mg.

– Inactive ingredient

Tablet core:

- Povidone
- Sodium Chloride
- Microcrystalline Cellulose
- Zinc Stearate

Film coat

- Opadry Complete Film Coating System 06F690000 Clear

– *MAL numbers*

MAL23046030AZ

Manufacturers

Novugen Pharma Sdn. Bhd.
No. 27, Jalan Lengku Teknologi 2,
Taman Teknologi Enstek Fasa 1,
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Product Registration Holder

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