Package leaflet: Information for the user

Sevelamer Hydrochloride Waymade 800 mg film-coated tablets
sevelamer hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sevelamer Hydrochloride Waymade is and what it is used for

Sevelamer Hydrochloride contains sevelamer as the active ingredient. It binds phosphate from food in the digestive tract and so reduces serum phosphate levels in the blood.

Sevelamer Hydrochloride is used to control the levels of phosphate in the blood of adult kidney failure patients on haemodialysis or peritoneal dialysis treatment.

Adult patients whose kidneys have failed and who are undergoing haemodialysis or peritoneal dialysis are not able to control the level of serum phosphate 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.

Sevelamer Hydrochloride may be used with other medicines which include calcium or vitamin D supplements to control the development of renal bone disease.

2. What you need to know before you take Sevelamer Hydrochloride Waymade

Do not take Sevelamer Hydrochloride:
- if you have low levels of phosphate in your blood (your doctor will check this for you).
- if you have bowel obstruction.
- if you are allergic to sevelamer or to any of the other ingredients of this medicine (listed in section 6).

Talk to your doctor while taking Sevelamer Hydrochloride Waymade:
- 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.

Warnings and precautions
Talk to your doctor before taking Sevelamer Hydrochloride if any of the following applies to you:
- if you are not on dialysis
- if you have swallowing problems
- if you have problems with motility (movement) in your stomach and bowel
- if you have symptoms of delayed emptying of stomach contents such as feeling of fullness, nausea and/or vomiting
- if you have prolonged diarrhoea or pain in the abdomen (symptoms of active inflammatory bowel disease)
- if you have undergone major surgery on your stomach or bowel.

Additional treatments:
Due to either your kidney condition or your dialysis treatment you may:
- develop a low or high level of calcium in your blood. Since Sevelamer Hydrochloride 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.

Changing treatment:
When you switch from another phosphate binder to Sevelamer Hydrochloride, your doctor might consider monitoring the levels of bicarbonate in your blood more closely because Sevelamer Hydrochloride may decrease the levels of bicarbonate.

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

Children and adolescents
The safety and efficacy in children (below the age of 18 years) has not been studied. Therefore Sevelamer Hydrochloride is not recommended for use in this population.

Other medicines and Sevelamer Hydrochloride Waymade
Tell your doctor if you are taking, have recently taken or might take any other medicines.

- Sevelamer Hydrochloride 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 Sevelamer Hydrochloride.
- The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (medicines used in transplant patients) may be reduced by Sevelamer Hydrochloride. Your doctor will advise you if you are taking these medicines.
- In certain people taking levothyroxine (a thyroid hormone) and Sevelamer Hydrochloride, increased levels of thyroid stimulating hormone (TSH, a substance in your blood which helps control your body's chemical functions) may very rarely be observed. Therefore your doctor may monitor the levels of TSH in your blood more closely.
- If you are taking medicine such as omeprazole, pantoprazole, or lansoprazole to treat heartburn, gastroesophageal reflux disease (GERD), or gastric ulcers, you should consult your doctor when

taking Sevelamer Hydrochloride.

Your doctor will check for interactions between Sevelamer Hydrochloride and other medicines on a regular basis.
In some cases where Sevelamer Hydrochloride 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 Sevelamer Hydrochloride intake, or he/she may consider monitoring the blood levels of that medicine.

Pregnancy and breast-feeding
The safety of Sevelamer Hydrochloride has not been established in pregnant or breast-feeding women. Sevelamer Hydrochloride should only be given to pregnant or breast-feeding women if clearly needed.

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.

Driving and using machines
Sevelamer Hydrochloride is unlikely to affect your ability to drive or to use machines.

Sevelamer hydrochloride tablets contain Sorbitol
Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take Sevelamer Hydrochloride Waymade

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. He will base the dose on your serum phosphate level. The recommended starting dose of Sevelamer Hydrochloride for adults and the elderly (>65 years) is one or two tablets with each meal 3 times a day.

Initially your doctor will check the levels of phosphate in your blood every 2-3 weeks and may adjust the dose of Sevelamer Hydrochloride when necessary (between 1 and 5 tablets of 800 mg per meal) to reach an adequate phosphate level.

The tablets must be swallowed whole. Do not crush, chew or break into pieces prior to swallowing.

Patients taking Sevelamer Hydrochloride should adhere to their prescribed diet and liquid intake.

If you take more Sevelamer Hydrochloride than you should
In the event of a possible overdose you should contact your doctor immediately.

If you forget to take Sevelamer Hydrochloride
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**.**

4. Possible side effects

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

Since constipation may be a preceding symptom in very rare cases of blockages in your intestine, it is important to inform your doctor or pharmacist of this symptom before or during the use of Sevelamer Hydrochloride.

The following side effects have been reported in patients taking Sevelamer Hydrochloride:
Very common (may affect more than 1 in 10 people):
nausea, vomiting.
Common (may affect up to 1 in 10 people):
diarrhoea, indigestion, abdominal pain, constipation, flatulence.
Uncommon (may affect up to 1 in 100 people):
increased acidity of the blood.
Very rare (may affect up to 1 in 10000 people):
hypersensitivity.
Not known (frequency cannot be estimated from the available data):
cases of itching, rash, abdominal pain, slow intestine motility (movement), inflammation of abnormal small pouches (called diverticula) in the large intestine, blockages in the intestine (signs include: severe bloating; abdominal pain, swelling or cramps; severe constipation), rupture in the intestine wall (signs include: severe stomach pain, chills, fever, nausea, vomiting, or a tender abdomen), serious inflammation of the large bowel (symptoms include: severe abdominal pain, stomach or intestine disorders, or blood in the stool [gastrointestinal bleeding]) and crystal deposit in the intestine have been reported.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sevelamer Hydrochloride Waymade

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special temperature storage conditions.
Keep the bottle tightly closed in order to protect from moisture.

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 to protect the environment.

6. Contents of the pack and other information

What Sevelamer Hydrochloride Waymade contains
- The active substance is sevelamer hydrochloride. Each tablet contains 800 mg sevelamer hydrochloride.
- The other ingredients are sorbitol (E 420), hypromellose (E 464), crosspovidone type B, silica colloidal anhydrous, magnesium stearate, opadry white (hypromellose (E 464), hydroxypropyl cellulose (E 463), macrogol 6000 (E 1521) and titanium dioxide (E 171)).

What Sevelamer Hydrochloride Waymade looks like and contents of the pack
Sevelamer hydrochloride Waymade tablets are film coated, white to off white, oval tablets debossed with 800 on one side and debossed with SH on other side. The tablets are packed in high density polyethylene bottles containing silica gel desiccant with a child resistant polypropylene closure and an induction seal. Do not swallow the desiccant.

Pack sizes are:
1 bottle of 30 film-coated tablets
1 bottle of 100 film-coated tablets

1 bottle of 180 film-coated tablets
multipacks containing 180 film-coated tablets (6 bottles of 30 tablets)
multipacks containing 360 film-coated tablets (2 bottles of 180 tablets)
multipacks containing 540 film-coated tablets (3 bottles of 180 tablets)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Waymade B.V.
Herikerbergweg 88, Amsterdam
1101 CM, Netherlands

Manufacturer:

Drehm Pharma GmbH
Grünbergstraße 15/3/3,
1120 Wien,
Austria

AcertiPharma B.V.
Boschstraat 51, 4811 GC, Breda,
Netherlands

This leaflet was last revised in 09/2023.