

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zemplar 4 micrograms Capsules, Soft Paricalcitol

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Zemplar is and what it is used for
2. Before you take Zemplar
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1 WHAT Zemplar IS AND WHAT IT IS USED FOR

Zemplar is a synthetic form of active vitamin D.

Active vitamin D is required for the normal functioning of many tissues in the body, including the parathyroid gland and bones. In people who have normal kidney function, this active form of vitamin D is naturally produced by the kidneys, but in kidney failure the production of active vitamin D is markedly reduced. Zemplar therefore provides a source of active vitamin D, when the body cannot produce enough and helps to prevent the consequences of low levels of active vitamin D, in patients with kidney disease (Stages 3, 4 and 5) namely high levels of parathyroid hormone which can cause bone problems.

2 BEFORE YOU TAKE Zemplar

Do not take Zemplar

- if you are allergic (hypersensitive) to paricalcitol or any of the ingredients of Zemplar.
- if you have very high levels of calcium or vitamin D in your blood.

Your doctor will be able to tell you if these conditions apply to you

Take special care with Zemplar

- Before the treatment begins, it is important to limit the amount of phosphorus in your diet.
- Phosphate-binding medicines may be needed to control phosphorus levels. If you are taking calcium-based phosphate binders, the doctor may need to adjust your dose.
- Your doctor will need to do blood tests to monitor your treatment.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines can affect the action of Zemplar or make side effects more likely.

It is particularly important to tell your doctor if you are taking ketoconazole (used to treat fungal infections such as candida or thrush), Cholestyramine (used for lowering cholesterol levels), medicines for the heart or for blood pressure (e.g. digoxin and diuretics or water pills) or medicines containing high calcium levels. It is also important to mention if you are taking medicines which

contain magnesium or aluminium e.g. some types of indigestion medicines (antacids) and phosphate-binders.

Ask your doctor or pharmacist for advice before taking any medicine.

Taking Zemplar with food and drink

Zemplar may be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or thinking of becoming pregnant, tell your doctor before taking Zemplar. There is no adequate data on the use of paricalcitol in pregnant women. Potential risk in human use is not known, therefore paricalcitol should not be used unless clearly necessary.

It is not known if paricalcitol passes into human breast milk. Tell your doctor before breast-feeding while taking Zemplar.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Zemplar should not affect your ability to drive or use machines.

Important information about some of the ingredients of Zemplar

This medicine contains a small amount of ethanol (an alcohol), less than 100mg per capsule, which may modify or increase the effect of other medicines. This could be harmful to people who suffer from liver disease, alcoholism, epilepsy, brain injury, or disease as well as in pregnant or breast-feeding women and children.

3 HOW TO TAKE Zemplar

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

Chronic Kidney Disease Stages 3 and 4

The usual dose is one capsule every day, or every other day, up to three times a week. Your doctor will use the results of your laboratory tests to decide the correct dose for you. Once Zemplar is started, the dose is likely to need adjusting, depending on how you respond to treatment. Your doctor will help determine the correct dose of Zemplar for you.

Chronic Kidney Disease Stage 5

The usual dose is one capsule every other day, up to three times a week. Your doctor will use the results of your laboratory tests to decide the correct dose for you. Once Zemplar is started, the dose is likely to need adjusting, depending on how you respond to treatment. Your doctor will help determine the correct dose of Zemplar for you.

Liver disease

If you have mild to moderate liver disease, your dose will not need to be adjusted. However, there is no experience in patients with severe liver disease.

Children

There is no information on the use of Zemplar capsules in children.

Elderly

There is a limited amount of experience of using Zemplar in patients aged 65 years or older. In general no overall differences in effectiveness or safety were seen between patients aged 65 years or older and younger patients.

If you take more Zemplar than you should

Too much Zemplar can cause abnormally high levels of calcium in the blood, which can be harmful. Symptoms which can appear soon after taking too much Zemplar may include a feeling of weakness and/or drowsiness, headache, nausea (feeling sick) or vomiting (being sick), a dry mouth, constipation, pains in muscles or bones and a metallic taste in the mouth.

Symptoms which can develop over a longer period of taking too much Zemplar include loss of appetite, drowsiness, weight loss, sore eyes, a runny nose, itchy skin, feeling hot and feverish, loss of sex drive and severe abdominal pain (due to an inflamed pancreas) and kidney stones. Your blood pressure may be affected and heart beat irregularities (palpitations) can occur. The results of blood and urine tests may show high cholesterol, urea, nitrogen and raised levels of liver enzymes. Zemplar may rarely cause mental changes including confusion, drowsiness, insomnia or nervousness.

If you take too much Zemplar, or experience any of the above, seek medical advice immediately.

If you forget to take Zemplar

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the dose that you have missed; simply continue to take Zemplar as previously directed (dose and time) by your doctor.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Zemplar

Unless your doctor tells you to stop your treatment, it is important to keep taking Zemplar as your doctor has directed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zemplar can cause side effect, although not everybody gets them.

Tell your doctor immediately if you notice any of the following side effects:

In patients with chronic kidney disease stage 3 and 4

The most common (at least 1 in 100 patients) side effects include: rash and stomach discomfort.

Less commonly (at least 1 in 1000 patients), allergic reactions (such as shortness of breath wheezing, rash, itching or swelling of the face and lips) itchy skin and hives may occur, as well as constipation, dry mouth, muscle cramps, dizziness and an unusual taste in the mouth. Changes in liver function tests may also occur.

If you experience an allergic reaction, please contact your doctor immediately.

In patients with chronic kidney disease stage 5

The most common (at least 1 in 100 patients) side effects are diarrhoea, heartburn (reflux or indigestion), decreased appetite, dizziness, breast pain and acne. Abnormal blood calcium levels can also occur.

The most common (at least 1 in 100 patients) side effects seen in patients during use of paricalcitol injection are: headache, unusual taste in mouth, itching, decreased levels of parathyroid hormone, increased levels of calcium, and increased levels of phosphorous.

Less common (at least 1 in 1000 patients) side effects seen in patients during use of paricalcitol injection are: irregular heartbeat, prolonged bleeding, liver function test abnormal, weight loss, heart stops beating, very fast heartbeat, low white blood cell count, low red blood cell count, swollen glands, stroke, mini-stroke, coma, fainting, dizziness, twitching, feeling of pins and needles, numbness, increased pressure in the eyes, pink eye, red eyes, earache, water in the lungs, nose bleed, shortness of breath, wheezing, cough, low blood flow to the intestines, anal bleeding, upset stomach,

difficulty swallowing, irritable bowel syndrome, diarrhoea, constipation, heartburn, vomiting, nausea, dry mouth, stomach discomfort, itchy rash, rash, blister, hair loss, hair growth, night sweats, injection site pain, skin burning sensation, joint pain, muscle pain, back pain, joint stiffness, muscle twitching, high levels of parathyroid hormone, loss of appetite, decreased appetite, blood infection, pneumonia, flu, cold, sore throat, vaginal infection, breast cancer, low blood pressure, high blood pressure, chest pain, abnormal walk, swelling in the legs, swelling, chest discomfort, fever, weakness, pain, tired, not feeling well, thirsty, feeling abnormal, breast pain, allergy, difficulty having an erection, disturbance of consciousness, confused, anxious, can not sleep, nervous, restless.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

5. HOW TO STORE Zemplar

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions..

Do not use Zemplar after the expiry date which is stated on the carton and label after abbreviation EXP used for expiry date. This expiry date refers to the last day of that month.


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.

6. FURTHER INFORMATION

What Zemplar contains

- The active substance is paricalcitol. Each soft capsule contains 4 micrograms of paricalcitol.
- The other ingredients are: medium chain triglycerides, ethanol, butylhydroxytoluene.
- The capsule shell contains: gelatin, glycerol, water, titanium dioxide (E 171), iron oxide yellow (E 172).
- The printing ink contains: propylene glycol, black iron oxide (E172), polyvinyl acetate phthalate, Macrogol 400, ammonium hydroxide.

What Zemplar looks like and contents of the pack

Zemplar Capsules, 4 micrograms, is an oval, gold soft capsule imprinted with  and ZK

Each carton contains either 1 or 4 foil blister packs. Each pack contains 7 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Abbott Laboratories Ireland Ltd, 4051 Kingswood Drive, Citywest Business Campus, Dublin 24.

Manufacturer: Aesica Queenborough Limited, Queenborough Kent ME11 5EL, United Kingdom.

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