Package leaflet: Information for the patient

Zemplar 1 microgram capsules, soft
paricalcitol

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 any 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 Zemplar is and what it is used for

Zemplar contains the active substance paricalcitol, which 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, namely high levels of parathyroid hormone which can cause bone problems. Zemplar is used in adult patients with kidney disease Stages 3, 4 and 5 and children aged 10 to 16 years with kidney disease Stages 3 and 4.

2. What you need to know before you take Zemplar

Do not take Zemplar

- if you are allergic to paricalcitol or any of the other ingredients of this medicine (listed in section 6).
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking 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.
- in some patients with chronic kidney disease stages 3 and 4, an increase in the blood levels of a substance called creatinine has been observed. However, this increase does not reflect a reduction in renal function.

Other medicines and Zemplar

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

Some medicines may affect the action of this medicine or may increase the likelihood of side-effects. It is particularly important to tell your doctor if you are taking any of the following medicines:

- to treat fungal infections such as candida or thrush (for example ketoconazole);
- to treat heart problems or high blood pressure (for example digoxin, diuretics or water pills);
- that contain a source of phosphate (for example, medicines to lower calcium levels in the blood);
- that contain calcium or Vitamin D, including supplements and multivitamins that can be bought without a prescription;
- that contain magnesium or aluminium (for example some types of indigestion medicines (antacids) and phosphate-binders);
- to treat elevated cholesterol levels (for example cholestyramine).

Zemplar with food and drink

Zemplar may be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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.

Driving and using machines

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

Zemplar contains ethanol (alcohol)

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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Chronic Kidney Disease Stages 3 and 4

In adult patients the usual initial 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

In adult patients the usual initial 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.

Renal transplant

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.

Use in children and adolescents

In children ages 10 to 16 years of age with chronic kidney disease Stages 3 or 4 the usual initial 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.

The efficacy of Zemplar in children with CKD Stage 5 has not been established.

There is no information on the use of Zemplar capsules in children under the age of 10 years.

Use in 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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

Common (may affect up to 1 in 10 people) side effects seen in patients during use of paricalcitol capsules include: increase in the blood levels of a substance called calcium, as well as the amount of calcium times the amount of another substance in the blood called phosphate (in patients with significant chronic kidney disease). Phosphate blood levels also may be increased.

Uncommon (may affect up to 1 in 100 people) side effects seen in patients during use of paricalcitol capsules include allergic reactions (such as shortness of breath, wheezing, rash, itching, or swelling of the face and lips), decreased levels of parathyroid hormone, diarrhoea, muscle cramps, nausea, dizziness, stomach discomfort or pain, vomiting, weakness, tired, rash, pneumonia, decreased appetite, decreased levels of calcium, unusual taste in the mouth, irregular heartbeat, constipation, dry mouth, heartburn (reflux or indigestion), acne, itchy skin, hives, muscle pain, breast tenderness, not feeling well, swelling in the legs, pain, increased levels of creatinine, changes in liver function tests, and headache.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects (see details below).
By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.

Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

5. How to store Zemplar

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

This medicinal product does not require any special storage conditions.

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

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 Zemplar contains

- The active substance is paricalcitol. Each soft capsule contains 1 microgram of paricalcitol.
- The other ingredients are: medium chain triglycerides, ethanol, butylhydroxytoluene.
- The capsule shell contains: gelatin, glycerol, water, titanium dioxide (E 171), iron oxide black (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 1 microgram capsules, is an oval, grey soft capsule imprinted with ZA.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
In Ireland; AbbVie Limited, Citywest Business Campus, Dublin 24, Ireland
In the UK; AbbVie Ltd., Maidenhead, SL6 4UB, UK

Manufacturer: Aesica Queenborough Limited, Queenborough, Kent ME11 5EL, United Kingdom
Manufacturer: AbbVie Deutschland GmbH&Co.KG, Knollstrasse, 67061 Ludwigshafen Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria: Земплар 1 микрограм меки капсули
Cyprus: Zemplar 1 μικρογραμμάριο καψάκια, μαλακά
Czech Republic: Zemplar
Estonia: Zemplar, 1 mikrogramm pehmekapslid
Finland: Zemplar 1 mikrogramma, pehmeät kapselit
Germany: Zemplar 1 Mikrogramm Weichkapseln
Greece: Zemplar 1 μικρογραμμάριο καψάκια, μαλακά
Hungary: Zemplar 1 mikrogramm lágy kapszula
Ireland: Zemplar 1 microgram capsules, soft
Italy: Zemplar 1 microgrammo capsule molli

Latvia: Zemplar 1 mikrograma mīkstās kapsulas
Lithuania: Zemplar 1 mikrogramas minkštosios kapsulės
Netherlands: Zemplar 1 microgram capsules, zacht
Norway: Zemplar 1 mikrogram kapsler, myke
Portugal: Zemplar 1 micrograma cápsulas moles
Romania: Zemplar 1 microgram, capsule moi
Slovakia: Zemplar 1 mikrogram mäkké kapsuly
Slovenia: Zemplar 1 mikrogram mehke kapsule
Spain: Zemplar 1 microgramo cápsulas blandas
Sweden: Zemplar 1 mikrogram kapsel, mjuk
United Kingdom: Zemplar 1 microgram capsules, soft

This leaflet was last revised in March 2019.

For information in large print, tape, CD or Braille, phone 01628 561090 (UK) or 01 428 7900 (Ireland).