ZEMPLAR® CAPSULES

Paricalcitol (1mcg, 2mcg, 4mcg)

What is in this leaflet

What Zemplar Capsule is used for

Zemplar capsules are indicated for the prevention and treatment of secondary hyperparathyroidism (excess parathyroid hormone in the bloodstream due to overactivity of parathyroid glands) associated with chronic renal insufficiency (chronic kidney disease stage 3 and 4) patients and chronic renal failure (chronic kidney disease stage 5) patients on hemodialysis or peritoneal dialysis (a treatment for kidney failure using an advanced dialysis machine to remove waste products from the blood).

How Zemplar Capsule works

Zemplar capsule contains the active ingredient, paracalcitol, which is a man-made active form of vitamin D.
Active vitamin D is required for the normal function 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.

Before you use Zemplar Capsule

- *<u>When you must not use it</u>*

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

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.

- *<u>Before you start to use it</u>*

Before the treatment begins, it is important to limit the amount of phosphorus in your diet.

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

- *<u>Taking other medicines</u>*

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:

- prescription based phosphate, high doses of calcium-containing products or vitamin D-related medicinal products
- 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).
- medicines containing high calcium levels
- 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

How to use Zemplar Capsule

- *<u>How much to use</u>*

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 less than 18 years of age.

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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.

- *When to use it*

Zemplar may be taken with or without food. Zemplar should only be taken as instructed by your doctor.

- *How long to use it*

Continue taking Zemplar Capsule for as long as your doctor recommends.

- *If you forget to use it*

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 use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many Zemplar Capsules may cause:
- hypercalcemia (a condition in which the calcium level in your blood is above normal.)
- hypercalciuria (excessive urinary calcium excretion)
- hyperphosphatemia (an electrolyte disturbance in which there is an abnormally elevated level of phosphate in the blood)
- over suppression of parathyroid hormone (limited output of parathyroid hormone)

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Zemplar Capsules.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Zemplar Capsule to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

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

Side effects

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

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

In chronic kidney disease stage 3 and 4.
The common side effect (at least 1 in 100 patients) 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 urticaria (a raised, itchy rash that appears on the skin) 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 chronic kidney disease stage 5
The 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.
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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and disposal of Zemplar Capsule

- *Storage*
  - Keep out of the reach and sight of children.
  - Store Zemplar Capsules at 25°C (77°F).
  - 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.

- *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*

Zemplar 1 mcg - soft gelatin capsules, oval, grey.
Zemplar 2 mcg – soft gelatin capsules, oval, orange-brown.
Zemplar 4mcg – soft gelatin capsules, oval, gold.

Each bottle contains 30 capsules.

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- *Ingredients*

Active ingredient

The active substance is paricalcitol. Each soft capsule contains 1, 2 and 4 microgram of paricalcitol

Inactive ingredients

The other ingredients are: medium chain triglycerides (fractionated coconut oil), ethanol, butylhydroxytoluene.

- The capsule shell contains: gelatin, glycerol, water, titanium dioxide (E 171), iron oxide black (E 172) – 1 mcg capsule only; iron oxide red – 2mcg capsule only; and iron oxide yellow – 2mcg and 4 mcg capsules.

MAL number(s):

Zemplar Capsule 1mcg
MAL20071708AC
Zemplar Capsule 2mcg
MAL20071709AC
Zemplar Capsule 4mcg
MAL20071710AC

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