

QALYVIZ SOFT CAPSULE

Calcitriol (0.25mcg)

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What QALYVIZ is used for

Active substance of QALYVIZ, calcitriol belongs to a group of medicines called 'vitamin D metabolites'.

QALYVIZ is used to treat the following:

- Bone disease in people with kidney problems (renal osteodystrophy).
- Weakening of the bones in women after the menopause (post-menopausal osteoporosis).

How QALYVIZ works

QALYVIZ works by making your body absorb more calcium from your diet. This helps to form healthy bones and reduce bone damage.

Before you use QALYVIZ

- When you must not use it

Do not take this medicine if:

- you are allergic to *calcitriol* or any other ingredients of this medicine (listed in Product Description) or any other 'vitamin D metabolite' medicines (used to treat bone disease). These include alfacalcidol and colecalciferol.
- you have high levels of calcium in your blood (hypercalcemia)
- you have extra deposits of calcium in your body (metastatic calcification).
- you are unwell because of high levels of vitamin D in your body.

- Before you start to use it

QALYVIZ contains sorbitol. If you have been told by your doctor that you have intolerance to some sugars, such as lactose, contact your doctor before taking QALYVIZ.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant or planning for pregnancy before using QALYVIZ. If you realize that you are pregnant during the treatment consult your doctor immediately.

You can take QALYVIZ if you are breast-feeding. However, your doctor will take blood samples from you and your child to check that there are no unwanted effects.

- Taking other medicines

Tell your doctor if you are taking any other medicines, in particularly any of the following:

- Other medicines containing vitamin D.
- Diuretics (used to treat high blood pressure). These include bendroflumethiazide, chlortalidone and indapamide.
- Medicines like digoxin or digitoxin (used to treat heart disease).
- Medicines containing magnesium, such as antacids (used to treat indigestion).
- Phenytoin or phenobarbital (used to treat epilepsy)
- Steroid medicines, such as hydrocortisone, prednisolone and dexamethasone.
- Cholestyramine, or other 'ion-exchange resins' (used to treat high levels of cholesterol in your blood).

Also tell your doctor or pharmacist if you have taken a medicine containing vitamin D over the last few months that has long-lasting effects. These medicines include ergocalciferol and colecalciferol.

How to use QALYVIZ

- How much to use

Always take QALYVIZ exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

While you are taking QALYVIZ, your doctor will want you to have regular blood tests to check that the level of calcium in your blood does not get too high.

Swallow the capsules whole with a little water.

Bone disease in people with kidney problems (renal osteodystrophy)

- The usual starting dose for adults and elderly people is one 0.25 microgram capsule once a day.
- After 2 to 4 weeks your doctor may start increasing your dose slowly by 0.25 microgram at a time.
- Eventually, depending on your blood test results, your doctor may need to adjust your dose again. Doctor may ask you to take QALYVIZ two or three times a week instead of every day. The maximum dose each week is 12 micrograms.

Bone disease after the menopause (post-menopausal osteoporosis)

- The usual dose for adult and elderly women is one 0.25 microgram capsule twice a day.

Use in children

Although not used in children, your doctor will select the appropriate dose.

Use in elderly

Dose adjustment is not required in elderly patients. Your serum calcium and creatinine levels should be monitored by your doctor.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that the doctor recommends.

- If you forget to use it

If you forget to take the dose, skip the missed dose. Then take the next dose as normal. Do not take a double dose to make up for the missed 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 use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many capsules, you may get too much calcium in your blood (hypercalcemia). The signs include loss of appetite, weight loss, nausea, vomiting, constipation, headache and feeling sluggish, drowsy or weak.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are using QALYVIZ.

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

Take QALYVIZ only with a doctor's prescription.

- Things you must not do

Do not stop using this medicine without advice from your doctor. This is because weakness of your bones needs long term treatment.

Do not use any new medicines without consulting your doctor or pharmacist.

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

- Things to be careful of

Driving and using machines

QALYVIZ is not likely to affect your ability to drive or use machines.

If this medicine makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Possible side effects are:

Rare:

**Effects on high levels of calcium in your blood*

- The signs include loss of appetite, weight loss, headache and feeling sluggish, drowsy or weak.
- Very high levels of calcium in your blood may lead to high temperature (fever), feeling thirsty, dehydration, passing more water than normal (polyuria), constipation, stomach pain, blockage of the bowel and an uneven heartbeat (arrhythmia). There may be infections in the bladder and normal growth may stop.
- Occasionally, mental problems may occur. Also there may be deposits of calcium in areas other than your bone (for example, in your kidneys as 'kidney stones'). Your doctor may change your dose of QALYVIZ if this happens.

** Effects on Liver*

- Changes in liver function (can be determined by blood tests)

** Hypersensitivity reactions*

- Skin disorders such as pruritus, rash, hives and severe redness (erythematous)

** Other*

- Nausea, vomiting

Unknown:

- Urinary tract infections

- Nutritional disorder, any disease related to malnutrition (dystrophy)
- Indifference (apathy)

Visit your doctor or pharmacist immediately if you experience any side effects after using 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 npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of QALYVIZ

- Storage

Keep QALYVIZ out of sight and reach of children and in its package.

Store at room temperature 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

QALYVIZ is with half of it is brown-orange to red-orange colored, opaque soft gelatin capsule. It is available in blister packages containing 30 capsules.

- Ingredients

- Active ingredient
Calcitriol

- Inactive ingredients
Butylhydroxyanisole, butylhydroxytoluene, medium chain triglyceride, gelatin (bovine gelatin), glycerin, sorbitol liquid, purified

water, titanium dioxide, yellow iron oxide, red iron oxide.

- MAL number:

MAL*****

Manufacturer

DEVA Holding A.Ş.
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No: 134303 Küçükçekmece – Istanbul,
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Product Registration Holder

Eucogen Sdn Bhd
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