

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

ORTHOCOLE 5 600 (tablets)

Alendronic acid 70 mg / Colecalciferol 140 µg (5 600 IU vitamin D₃)

Contains sugar: lactose (59,14 mg) and sucrose (27,49 mg)

Read all of this leaflet carefully before you start taking ORTHOCOLE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ORTHOCOLE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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1. What ORTHOCOLE is and what it is used for

Alendronate is a member of a class of non-hormonal medicines called bisphosphonates. ORTHOCOLE helps to rebuild bone and makes bone less likely to fracture.

Vitamin D is an essential nutrient, required for calcium absorption and healthy bones. The body can only absorb calcium properly from our food if it has enough vitamin D.

Your doctor has prescribed ORTHOCOLE to treat your osteoporosis and to help make sure you get enough vitamin D. This will reduce the risk of developing fractures.

2. What you need to know before you take ORTHOCOLE

Do not take ORTHOCOLE

- if you are hypersensitive (allergic) to alendronic acid, colecalciferol or any of the other ingredients of ORTHOCOLE (listed in section 6),
- if you have certain disorders of the oesophagus (the tube that connects your mouth with your stomach),
- if you cannot stand or sit upright for at least 30 minutes,
- if your doctor has told you that you have low blood calcium,
- if you are pregnant or breastfeeding your baby,
- if you are less than 18 years of age (ORTHOCOLE is not indicated for children and should not be given to them),
- if you have severe renal insufficiency (poor kidney function).

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Warnings and precautions

Take special care with ORTHOCOLE. Tell your doctor or pharmacist before taking ORTHOCOLE if:

- you have, or have recently had, any swallowing or digestive problems,

- you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking ORTHOCOLE and call your doctor. Oesophageal reactions may worsen if you continue to take ORTHOCOLE after developing symptoms suggesting irritation of the oesophagus,
- your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus),
- you have inflammation of your stomach lining (gastritis), inflammation of the first part of your small intestine (duodenitis), or ulcers, or if you have had a peptic (stomach) ulcer within the previous year, active gastrointestinal bleeding or surgery of your upper gastrointestinal tract,
- you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome),
- you have poor dental health, gum disease, a planned dental extraction or if you do not receive routine dental care,
- you have cancer, or if you are undergoing chemotherapy or radiotherapy, have poorly fitting dentures, extraction of a tooth or take a high dose over a long time as you may have a higher risk of developing bone damage in the jaw (osteonecrosis) with delayed healing and infection. Signs of osteonecrosis of the jaw can include pain in the mouth, and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. Tell your doctor straight away if you get any of these symptoms,
- you are taking angiogenesis inhibitors (medicines used to block the growth of blood vessels that support growth of a tumour) or corticosteroids (such as prednisone or dexamethasone) which are used in the treatment of such conditions as asthma, rheumatoid arthritis, and severe allergies,
- you are or have been a smoker (as this may increase the risk of dental problems),

- if you have hypocalcaemia (too low calcium levels in blood) and/or deficiency (too low blood levels) of vitamin D or parathyroid hormone (hypoparathyroidism); your doctor will prescribe corrective treatment and monitor these levels during treatment. The content of vitamin D in ORTHOCOLE is not suitable for the correction of vitamin D deficiency,
- if you have anaemia (a condition that develops when you have a lower-than-normal amount of healthy red blood cells); your doctor will treat you to correct these levels before treatment with ORTHOCOLE,
- if you have blood cancer (leukaemia), cancer of the body's disease-fighting network (lymphoma) or a disease that causes the growth of inflammatory cell collections most often in the lungs and lymph nodes (sarcoidosis). Your doctor may need to monitor your blood levels closely.

Tell your doctor straight away if you get any of the following symptoms or diseases as it could be due to a serious disorder:

- Bone, muscle or joint pain.
- Pain, swelling, tenderness and/or bruising in your thigh, hip or groin. This could be an indication of stress fractures in your leg bone (atypical fractures of the femur). Your doctor will indicate the correct treatment for this.
- Ear pain, itching, discharge and hearing loss, as these signs may be due to osteonecrosis (bone death) of the external auditory canal (outer ear canal).

You may be advised to have a dental check-up before starting treatment with ORTHOCOLE. It is important to maintain good oral hygiene when being treated with ORTHOCOLE. You should have routine dental check-ups throughout your treatment, and you should contact your doctor or dentist if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling.

Irritation, inflammation or ulceration of the gullet (oesophagus – the tube that connects your mouth with your stomach) often with symptoms of chest pain, heartburn, or difficulty or pain upon swallowing may occur, especially if you do not drink a full glass of water and/or if you lie down less than 30 minutes after taking ORTHOCOLE. These side effects may worsen if you continue to take ORTHOCOLE after developing these symptoms.

Children and adolescents

ORTHOCOLE should not be given to children and adolescents.

Other medicines and ORTHOCOLE

Always tell your healthcare provider if you are taking any other medicine. This includes all complementary or traditional medicines.

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of ORTHOCOLE if taken at the same time. Therefore, it is important that you follow the advice given in section 3 and wait at least 30 minutes before taking any other oral medicines or supplements.

Certain medicines for rheumatism or long-term pain called NSAIDs (e.g. acetylsalicylic acid or ibuprofen) might cause irritation to the stomach and intestinal lining. Therefore, caution should be used when these medicines are taken at the same time as ORTHOCOLE.

It is likely that certain medicines or food additives may prevent the vitamin D in ORTHOCOLE from getting into your body, including artificial fat substitutes, mineral oils, the weight loss medicine, orlistat, and the cholesterol-lowering medicines, cholestyramine and colestipol.

Medicines for fits (seizures) (like phenytoin or phenobarbital), cimetidine (used for stomach ulcers) and thiazides (water tablets) may decrease the effectiveness of vitamin D. Your medical practitioner will decide if you need to take additional vitamin D supplements if you take these medicines.

ORTHOCOLE with food and drink

It is likely that food and beverages (including mineral water) will make ORTHOCOLE less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3. You must wait at least 30 minutes before taking any food and beverages except water.

Pregnancy, breastfeeding and fertility

ORTHOCOLE is only intended for use in postmenopausal women. Do not take ORTHOCOLE if you are or think you may be pregnant, or if you are breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ORTHOCOLE.

Driving and using machines

Side effects such as blurred vision, dizziness and severe bone, muscle or joint pain were reported with ORTHOCOLE, which may affect your ability to drive or operate machinery (see section 4). If you experience any of these side effects, you should not drive until you feel better.

It is not always possible to predict to what extent ORTHOCOLE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ORTHOCOLE affects you.

ORTHOCOLE contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ORTHOCOLE

Do not share medicines prescribed for you with any other person.

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

The usual dose is one ORTHOCOLE tablet **once a week**.

Follow these instructions carefully:

1. Choose the day of the week that best fits your schedule. Every week, take one ORTHOCOLE tablet on your chosen day.

It is very important to follow instructions 2, 3, 4 and 5 to help the ORTHOCOLE tablet reach your stomach quickly and help reduce the chance of irritating your gullet (oesophagus - the tube that connects your mouth with your stomach).

2. After getting up for the day and before taking any food, drink, or other medicine, swallow your ORTHOCOLE tablet whole with a full glass of water only (not mineral water) (not less than 200 ml), so that ORTHOCOLE is adequately absorbed.
 - Do not take with mineral water (still or sparkling).
 - Do not take with coffee or tea.
 - Do not take with juice or milk.

Do not crush or chew the tablet or allow it to dissolve in your mouth because of the possibility of mouth ulceration.

3. Do not lie down — stay fully upright (sitting, standing or walking) — for at least 30 minutes after swallowing the tablet. Do not lie down until after your first food of the day.
- 4 Do not take ORTHOCOLE at bedtime or before getting up for the day.
- 5 If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking ORTHOCOLE and contact your doctor.
- 6 After swallowing your ORTHOCOLE tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. ORTHOCOLE is effective only if taken when your stomach is empty.

It is important that you continue taking ORTHOCOLE for as long as your doctor prescribes it.

If you have the impression that the effect of ORTHOCOLE is too strong or too weak, tell your doctor or pharmacist.

If you take more ORTHOCOLE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you take too many tablets by mistake, drink a full glass of milk and contact your doctor immediately. Do not make yourself vomit, and do not lie down.

If you forget to take ORTHOCOLE

If you miss a dose, just take one tablet on the morning after you remember. *Do not take two tablets on the same day.* Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you stop taking ORTHOCOLE

It is important that you take ORTHOCOLE for as long as your doctor prescribes the medicine. Since it is not known how long you should take ORTHOCOLE, you should discuss the need to stay on this medicine with your doctor periodically to determine if ORTHOCOLE is still right for you.

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

4. Possible side effects

ORTHOCOLE can have side effects.

Not all side effects reported for ORTHOCOLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ORTHOCOLE, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking ORTHOCOLE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- hives, rash, or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ORTHOCOLE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heartburn; difficulty swallowing; pain upon swallowing; ulceration of the gullet (oesophagus - the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or difficulty or pain upon swallowing,
- pain in the mouth, and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis) generally associated with delayed healing and infection, often following tooth extraction. Contact your doctor and dentist if you experience such symptoms,
- unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone,
- bone, muscle and/or joint pain which is sometimes severe,
- Stevens-Johnson syndrome (a condition that starts with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), toxic epidermal necrolysis (TEN) (a life-threatening skin disorder with symptoms such as a painful red area that spreads quickly, skin peeling without blisters, raw areas of skin) or other serious skin disorders.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache;

- abdominal pain; uncomfortable feeling in the stomach or belching after eating; constipation; full or bloated feeling in the stomach; diarrhoea; flatulence, acid regurgitation (bringing up small quantities of undigested food).

Less frequent side effects:

- talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection.
These could be signs of bone damage in the ear,
- nausea,
- black or tar-like stools,
- mouth ulcers,
- narrowing of the gullet (oesophagus – the tube that connects your mouth with your stomach),
- stomach or peptic ulcers (sometimes severe or with bleeding),
- rash; redness of the skin.

The following side effects have been reported, but the frequency for them to occur is not known:

- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth,
- dizziness, vertigo
- taste disturbance
- blurred vision; pain or redness in the eye,
- vomiting
- irritation or inflammation of the gullet (oesophagus – the tube that connects your mouth with your stomach) or stomach
- perforation of the gullet
- hair loss; itching

- rash made worse by sunlight
- severe bone, joint or muscle pain that hinders movement, joint swelling
- unusual thighbone fracture
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment
- tiredness
- swelling in the hands or legs
- laboratory test results indicating decreased calcium and phosphate in the blood.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ORTHOCOLE.

5. How to store ORTHOCOLE

Store all medicines out of reach of children.

Store at or below 25 °C in the original blister to protect from moisture and light.

Do not store in a bathroom.

Do not use this medicine after the expiry date which is stated on the carton and the blister.

The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ORTHOCOLE contains

Each ORTHOCOLE 5 600 tablet contains 70 mg alendronic acid (as alendronate sodium trihydrate) and 140 micrograms (5 600 IU) colecalciferol (vitamin D₃).

The other ingredients are lactose, microcrystalline cellulose (E460), croscarmellose sodium, magnesium stearate (E572), sunflower oil, refined, butylhydroxytoluene (E321), gelatin, sucrose, maize starch and aluminium magnesium silicate.

What ORTHOCOLE looks like and contents of the pack

ORTHOCOLE 5 600 tablets are available as white to off-white, modified rectangle-shaped tablets, mottled, engraved with 5600 on one side.

ORTHOCOLE 5 600 IU tablets are packed in PA/ALL/PVC – Aluminium foil (Alu-Alu blister) foil blister strips. Each pack contains 4 tablets.

Holder of the Certificate of Registration

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Access to the corresponding Professional Information

Please refer to the SAHPRA Repository of Professional Information and Patient Information

Leaflets: <https://www.sahpra.org.za/pi-pil-repository/>.