1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PREOVIDLEN 70 mg/ 5 600 IU tablets

Alendronic acid, cholecalciferol

Contains sugar: Lactose monohydrate 59,14 mg, sucrose 27,49 mg

Read all of this leaflet carefully before you start taking PREOVIDLEN

- 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.
- PREOVIDLEN 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

1. What PREOVIDLEN is and what it is used for

PREOVIDLEN contains the active substances alendronic acid (alendronate) and cholecalciferol (vitamin D_3).

PREOVIDLEN belongs to a group of medicines called non-hormonal bisphosphonates.

PREOVIDLEN is used in women to treat post-menopausal osteoporosis (a disease that weakens the bones) and to help make sure they get enough vitamin D. This will reduce the risk of developing fractures.

2. What you need to know before you take PREOVIDLEN

Do not take PREOVIDLEN:

- if you are hypersensitive (allergic) to alendronic acid, cholecalciferol or any of the other ingredients of PREOVIDLEN (listed in section 6).
- if you have certain problems with your oesophagus (the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing.
- 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 have kidney problems.
- if you are pregnant or breastfeeding.
- if the patient is a child.

Warnings and precautions

Take special care with PREOVIDLEN:

- if you have, or have recently had, any swallowing or digestive problems including disease of the oesophagus (the tube that connects your mouth with your stomach), inflammation of the lining of the stomach (gastritis) and part of your small intestine (duodenitis), a sore in the lining of your stomach (ulcer) and active bleeding from your stomach.

- if you recently had surgery in your upper stomach area (gastrointestinal tract).
- if your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus).
- if you have irritation, inflammation or ulceration of the 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 PREOVIDLEN. These side effects may worsen if you continue to take PREOVIDLEN after developing these symptoms.
- if you have poor dental health, gum disease, a planned dental extraction or you don't receive routine dental care.
- if you have cancer. This may increase your risk of developing damage in the jaw (osteonecrosis) generally associated with delayed healing and infection.
- if you are undergoing chemotherapy or radiotherapy, taking angiogenesis inhibitors (such as bevacizumab, or thalidomide) which are used in the treatment of cancer and taking corticosteroids (such as prednisone or dexamethasone) which are used in the treatment of such conditions as asthma, rheumatoid arthritis, and severe allergies. This may also increase your risk of developing damage in the jaw (osteonecrosis) generally associated with delayed healing and infection.
- if you are or have been a smoker (as this may increase the risk of dental problems).
- if you experience pain or discharge from the ear, or chronic ear infection as PREOVIDLEN can cause osteonecrosis (a bone disease) of the external auditory canal (i.e. from the opening of the ear to the eardrum).
- if you have bone, joint and/or muscle pain.
- if you experience thigh, hip or groin pain as this can be an indication of a fracture of the thigh bone.

- if you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome).
- if you may have been advised to have a dental check-up before starting treatment with PREOVIDLEN.
- if you have low calcium levels and produce low levels of parathyroid hormone (a hormone needed to keep your calcium and phosphorus levels balanced).
- if you have cancer of the blood (leukaemia), lymph nodes (lymphoma) or a condition that causes lumps or nodules to form in your organs (sarcoidosis). PREOVIDLEN may increase the magnitude of high calcium levels in your blood (hypercalcaemia) and excess calcium in your urine (hypercalciuria).

It is important to maintain good oral hygiene when being treated with PREOVIDLEN. 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.

Children

There is no experience with PREOVIDLEN in children younger than 18 years.

Other medicines and PREOVIDLEN

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Calcium supplements, antacids, and some oral medicines as they will interfere with the absorption of PREOVIDLEN if taken at the same time. Therefore, it is important that you wait at least 30 minutes before taking any other oral medicines or supplements.

- Non-steroidal anti-inflammatory drugs (NSAIDs), used for the treatment of pain, swelling and inflammation due to injuries or short-term treatment of acute gout (e.g. acetylsalicylic acid or ibuprofen), might cause irritation to the stomach and intestine lining. Therefore, caution should be used when these medicines are taken at the same time as PREOVIDLEN.
- Medicines for fits (seizures) (e.g. phenytoin or phenobarbital) may decrease the effectiveness of vitamin D. Additional vitamin D supplements may be considered on an individual basis.
- Olestra, used in the preparation of otherwise high-fat food, thereby lowering or eliminating their fat content. Olestra may impair the absorption of vitamin D contained in PREOVIDLEN.
- Mineral oils, used for the treatment of constipation, may impair the absorption of vitamin D contained in PREOVIDLEN.
- Orlistat, used to aid in weight loss, may impair the absorption of vitamin D contained in PREOVIDLEN.

- Bile acid sequestrates (e.g. colestyramine, cholesterol) used for to reduce low density lipoprotein (LDL) cholesterol levels, may impair the absorption of vitamin D contained in PREOVIDLEN.
- Cimetidine, used for the treatment of heartburn, may increase the breakdown of vitamin D contained in PREOVIDLEN.
- Thiazides e.g. hydrochlorothiazide, used to treat high blood pressure, may increase the breakdown of vitamin D contained in PREOVIDLEN.

PREOVIDLEN with food and drink

If taken at the same time, it is likely that food and beverages (including mineral water), calcium supplements, antacids and some oral medicines will likely reduce the absorption of PREOVIDLEN.

PREOVIDLEN must be taken at least 30 minutes before the first food, beverage, or medication of the day with plain water only.

Pregnancy and breastfeeding

You should not take PREOVIDLEN if you are pregnant or breastfeeding your baby.

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 PREOVIDLEN.

Driving and using machines

Since adverse reactions such as dizziness and headache have been reported in patients receiving PREOVIDLEN, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that PREOVIDLEN does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

It is not always possible to predict to what extent PREOVIDLEN 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 PREOVIDLEN affects you.

PREOVIDLEN 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 PREOVIDLEN.

TEOVILEN FORTE contains less the 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take PREOVIDLEN

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

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

The usual dose of PREOVIDLEN is:

One PREOVIDLEN tablet once a week.

Follow these instructions carefully.

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

It is very important to follow instructions 2), 3), 4) and 5) to help the PREOVIDLEN tablet reach your stomach quickly and help reduce the chance of irritating your 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 PREOVIDLEN tablet whole with a full glass of water only (not mineral water) (not less than 200 ml), so that PREOVIDLEN 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 developing sores in your mouth.

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 PREOVIDLEN 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 PREOVIDLEN and contact your doctor.

6) After swallowing your PREOVIDLEN tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. PREOVIDLEN is effective only if taken when your stomach is empty.

Your doctor will tell you how long your treatment with PREOVIDLEN will last.

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

If you take more PREOVIDLEN than you should

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

Low blood calcium (hypocalcaemia), low levels of phosphate in the blood (hypophosphataemia) and upper gastrointestinal adverse reactions, such as upset stomach, heartburn, oesophagitis, gastritis, or ulcer, may result from oral overdose.

If you forget to take PREOVIDLEN

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

If you have missed a dose of PREOVIDLEN, take the dose that you have missed on the morning after you remember. Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

PREOVIDLEN can have side effects.

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

If any of the following happens, stop taking PREOVIDLEN 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,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN).

These are all very serious side effects. If you have them, you may have had a serious reaction to PREOVIDLEN. 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:

- Ear pain, discharge from the ear, and/or an ear infection as these could be signs of bone damage in the ear (osteonecrosis of the external auditory canal),
- black or tar-like stool (melena),
- 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 (osteonecrosis of the jaw),

- development of a hole or sore (ulcer) or bleeding in the upper gastrointestinal tract (upper gastrointestinal PUB's) with symptoms such as stomach cramps, bloody or black stools, feeling tired and weak and blood in vomit,
- increased heart rate, rapid breathing, low blood pressure, fever, chills, vomiting which may include blood; these may be signs that you have holes in your oesophagus (oesophageal perforations).

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, dizziness,
- a sensation of whirling and loss of balance (vertigo),
- abdominal pain, pain or an uncomfortable feeling in the upper middle part of your stomach area (dyspepsia), constipation, diarrhoea, a build-up of gas in the stomach (flatulence), an open sore in the lining of your oesophagus (oesophageal ulcer), difficulty swallowing foods or liquids (dysphagia), bloating and swelling in the belly area (abdominal distension), contents from your stomach moving back up into your oesophagus (acid regurgitation),
- loss of hair (alopecia),
- bone, muscle or joint pain which is sometimes severe, joint swelling,
- abnormal physical weakness or lack of energy (asthenia), swelling of lower legs or hands (peripheral oedema).

Less frequent side effects:

- Symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth (hypocalcaemia),

- changes or impaired sense of taste (dysgeusia),
- inflammation of the eye (uveitis, scleritis, or episcleritis),
- nausea, vomiting, inflammation of the lining of the stomach (gastritis), inflammation of the oesophagus (oesophagitis), valve between the lower end of the oesophagus and the stomach does not close tightly (oesophageal erosions),
- broken hip bone and the long bone in the upper part of the leg (atypical subtrochanteric and diaphyseal femoral fractures),
- pain in the muscles (myalgia), feeling of being ill or having no energy (malaise) and high temperature (fever), (typically in association with start of treatment).

Side effects with an unknown frequency:

- Decreased calcium and phosphate levels in the blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 (whoumc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store PREOVIDLEN

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Keep blister in carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 PREOVIDLEN contains

The active substances are 70 mg alendronic acid as alendronate sodium trihydrate and 0,14 mg (5 600 IU) cholecalciferol (vitamin D3).

The other ingredients are aluminium magnesium silicate, butylhydroxytoluene, croscarmellose sodium, gelatin, lactose anhydrous, magnesium stearate, maize starch, microcrystalline cellulose, sucrose, sunflower oil.

What PREOVIDLEN looks like and contents of the pack

PREOVIDLEN are white to off-white, modified rectangle-shaped, mottled, tablets engraved with 5600 on one side.

Silver aluminium/aluminium blister containing 4 tablets, packaged in a cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

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

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088