

PATIENT INFORMATION LEAFLET
Information for the Patient about DensiMAX™ Tablets

Health Supplement

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS:

Not Scheduled.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DensiMAX™ tablets.

Read all of this leaflet carefully because it contains important information for you. DensiMAX™ tablets are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DensiMAX™ tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DensiMAX™ with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a registered healthcare practitioner if your symptoms worsen or do not improve.

WHAT DensiMAX™ TABLETS CONTAIN:

Each DensiMAX™ tablet contains:

ACTIVE INGREDIENT	QUANTITY	DAILY DOSAGE	RDA
Calcium (from Aquamin™*Lithothamnium calcareum)	450 mg	900 mg	90%
Magnesium (from Aquamin™*Lithothamnium calcareum)	31 mg	62 mg	19%
Vitamin D3 (Cholecalciferol)	240 IU	480 IU	80%
Trace minerals (from Aquamin™*Lithothamnium calcareum) 72 Trace minerals including Boron, Chloride, Iron, Phosphorus, Potassium, Selenium, Sodium, Zinc	444 mg	888 mg	

Inactive ingredients: gum acacia, sodium carboxy-methyl cellulose, and magnesium stearate.

DensiMAX™ tablets are free from sugar and lactose.

WHAT DensiMAX™ TABLETS ARE USED FOR:

DensiMAX™ tablets is a multi-mineral supplement that supports healthy bones and teeth and is a factor in the maintenance of good health. Calcium intake, when combined with sufficient Vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis

BEFORE YOU TAKE DensiMAX™ TABLETS:

Do NOT take DensiMAX™ tablets:

- If you are allergic to any of the ingredients in DensiMAX™ tablets.
- If you have abnormally high levels of calcium in the blood and/or excessive loss of calcium in the urine (see "Take special care with DensiMAX™ tablets").
- If you have high or low levels of phosphate in the blood (see "Take special care with DensiMAX™ tablets").
- Surgery (see "Take special care with DensiMAX™ tablets").

Take special care with DensiMAX™ tablets:

Please discuss the use of DensiMAX™ tablets with your pharmacist or registered healthcare practitioner if you:

- Suffer from have abnormally high levels of calcium in the blood and/or excessive loss of calcium in the urine. Conditions that lead to abnormally high levels of calcium in the blood include para-thyroid gland disorders, sarcoidosis, poor kidney function and bone cancer. Conditions that lead to abnormally low levels of calcium in the blood are kidney stones and kidney failure (see "Do NOT take DensiMAX™ tablets").
- Suffer from high or low levels of phosphate in the blood. You may have to arrange increased monitoring of your phosphate levels when starting or stopping treatment with DensiMAX™ tablets (see "Do NOT take DensiMAX™ tablets").
- Suffer from low levels of stomach acid. People with low levels of gastric acid absorb less calcium if it is taken on an empty stomach. However, low acid levels in the stomach do not reduce calcium absorption if calcium is taken with food (see "Do NOT take DensiMAX™ tablets").
- Are a smoker. Smokers absorb less calcium from the stomach. The dose of DensiMAX™ tablets may need to be adjusted if you smoke.
- Are undergoing surgery, discontinue use at least 2 weeks prior to the procedure (see "Do NOT take DensiMAX™ tablets").
- Take warfarin or other blood thinning medicines. You may have to arrange increased monitoring or your INR (International Normalised Ratio) levels when starting or stopping treatment with DensiMAX™ tablets (see "Taking other medicines with DensiMAX™ tablets").

The use of DensiMAX™ tablets in children and adolescents under 18 years of age is not recommended due to lack of adequate data (see "HOW TO TAKE DensiMAX™ TABLETS").

Taking DensiMAX™ tablets with food and drink:
DensiMAX™ tablets should be with meals with water.

Pregnancy and breastfeeding:

Use DensiMAX™ tablets under supervision of a pharmacist or registered healthcare practitioner.

If you are pregnant or breastfeeding your baby, please consult your pharmacist or registered healthcare practitioner for advice before taking DensiMAX™ tablets.

Driving and using machinery:

No studies on the effect on the ability to drive and use machinery have been performed. It is unlikely that DensiMAX™ tablets will impair your ability to drive or use machines. However, please exercise care when driving or operating machinery until you know how DensiMAX™ tablets affects you.

Important information about some of the ingredients of DensiMAX™ tablets:

DensiMAX™ tablets are sugar and lactose free.

Taking other medicines with DensiMAX™ tablets:

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

Please discuss the use of the following medicines in combination with DensiMAX™ tablets with your pharmacist or registered healthcare practitioner:

- Calcipotriene, a medicine similar to vitamin D, for the treatment of psoriasis.
 - Diltiazem for the treatment of high blood pressure, angina and heart rhythm disorders.
 - Lithium for the treatment of bipolar disorder.
 - Potassium sparing diuretics for the treatment of hypertension and management of congestive heart failure.
 - Skeletal muscle relaxants used to alleviate muscle spasms, pain, and hyperreflexia.
- The dose of the above medications may need to be adjusted when taken with DensiMAX™ tablets.

Also, discuss the use of the following medicines in combination with DensiMAX™ tablets with your pharmacist or registered healthcare practitioner:

- Raltegravir (an anti-retroviral medication). DensiMAX™ tablets may decrease its levels.
- Thiazide diuretics. DensiMAX™ tablets could increase calcium levels in the blood. Monitor your calcium and parathyroid function regularly if you are using DensiMAX™ tablets and thiazide diuretics in combination.
- Antacids as DensiMAX™ tablets may reduce the levels of magnesium.
- Anti-diabetic medicines. DensiMAX™ tablets may increase its effects. Monitor your blood sugar levels regularly if you are using DensiMAX™ tablets and anti-diabetic medicines in combination.
- Warfarin or other blood thinning medicines. DensiMAX™ tablets may potentially increase the effect of blood thinning medicines (see "Take special care with DensiMAX™ tablets").
- Bisphosphonates as DensiMAX™ tablets can influence the absorption and effectiveness of these medicines (see "HOW TO TAKE DensiMAX™ TABLETS").
- Levothyroxine, taken for hypothyroidism, as DensiMAX™ tablets may decrease its absorption (see "HOW TO TAKE DensiMAX™ TABLETS").
- Integrase inhibitors, used to treat HIV, as DensiMAX™ tablets may decrease the levels of this medication (see "HOW TO TAKE DensiMAX™ TABLETS").
- Tetracycline and quinolone antibiotics as DensiMAX™ tablets decreases the levels of this medication (see "HOW TO TAKE DensiMAX™ TABLETS").
- Sotalol as DensiMAX™ tablets decreases the levels of this medication (see "HOW TO TAKE DensiMAX™ TABLETS").
- Gabapentin as DensiMAX™ tablets decreases levels of this medication (see "HOW TO TAKE DensiMAX™ TABLETS").

HOW TO TAKE DensiMAX™ TABLETS:

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

Always take DensiMAX™ tablets exactly as directed. You should check with your pharmacist or registered healthcare practitioner if you are unsure.

DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

Adults (18 years and older):

Take 1 tablet twice daily with meals or as directed by your pharmacist or registered healthcare practitioner.

Children (under 18 years of age):

Not recommended for use (see "Take special care with DensiMAX™ tablets")

Bisphosphonates must be taken 30 min prior or at a different time of the day. Levothyroxin must be taken at least 4 hours apart from DensiMAX™ tablets. Integrase inhibitors, tetracycline and quinolone antibiotics, sotalol and gabapentin must be taken at least 2 hours before, or 4-6 hours after DensiMAX™ tablets (see "Taking other medicines with DensiMAX™ tablets").

DensiMAX™ tablets may be taken for a period of up to 12 weeks followed by an interval of 1 week after which the next 12-week cycle can commence. However, should you experience any adverse effects or any of the side effects indicated below please consult your pharmacist or registered healthcare practitioner.

If you take more DensiMAX™ tablets than you should:

If you take more DensiMAX™ tablets than you should, you may experience thirst, drowsiness, confusion, weakness, difficulty breathing, chest pain and unconsciousness.

In the event of over dosage, consult your pharmacist or registered healthcare practitioner. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take DensiMAX™ tablets:

Always take DensiMAX™ tablets as directed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose till the next dose is due, skip the missed dose and go back to your regular dosing schedule of one tablet twice daily. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

DensiMAX™ tablets may have side-effects.

Not all side-effects reported for DensiMAX™ tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DensiMAX™ tablets, please consult your pharmacist or registered healthcare practitioner for advice.

Serious side-effects that you (or a family member if you are unable to) should report to your pharmacist or registered healthcare practitioner immediately include:

- An allergic reaction which may present with shortness of breath, difficulty breathing, wheezing, hives, or itching, swelling of the face, tongue or whole body.
 - Chest pain, nausea, vomiting, constipation, abdominal pain, increased thirst & urination, fatigue, muscle weakness & pain, confusion, disorientation, difficulty talking, headaches, depression and poor appetite.
 - Blood in urine, fever and chills, severe stomach or back pain.
- Side-effects that you should report to your pharmacist or registered healthcare practitioner as soon as possible:
- Less or more urine than is normal for you.
 - Swollen face, feet and ankles.
 - Breath odour.
- Side-effects that you should report to your pharmacist or registered healthcare practitioner if they continue or become bothersome include:
- Gastrointestinal disturbances, such as:
 - Stomach discomfort, indigestion, diarrhoea, constipation, belching, acid reflux & heartburn, flatulence.

If you notice any side-effects not mentioned in this leaflet, please inform your pharmacist or registered healthcare practitioner.

STORING AND DISPOSING OF DensiMAX™ tablets:

Store at or below 25°C in a dry place.

Protect from light / moisture.

Do not take the tablets after the expiry date stated on the packaging material.

Return all unused tablets to your pharmacist.

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

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION OF DensiMAX™ tablets:

60 Tablets packed in a 125ml amber glass bottle with a seal and mustard gold screw cap in a product box with a package insert.

IDENTIFICATION OF DensiMAX™ tablets:

23 mm oblong off-white tablet.

REGISTRATION NUMBER / REFERENCE NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

Flora Force Health Products (Pty) Ltd.
Unit 3 Regent Park
Bell Crescent
Westlake
Cape Town
South Africa

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