



PAA144641

CALTRATE 600+D PATIENT INFORMATION LEAFLET

34.12 Category D - Complementary Medicine – Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S

PROPRIETARY NAME AND DOSAGE FORM:
CALTRATE® 600+D (Tablets)

Read all of this leaflet carefully because it contains important information for you.

CALTRATE 600+D is available without a doctor's prescription, for your use as a health supplement. Nevertheless you still need to use CALTRATE 600+D carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CALTRATE 600+D with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if you experience troubling symptoms.

WHAT CALTRATE 600+D CONTAINS:

The active substances are as follows:

Each CALTRATE 600+D tablet contains	Per tablet
Calcium*	600 mg
Vitamin D	400 IU

*1500 mg calcium carbonate equivalent to 600 mg elemental calcium.

The complete list of ingredients is: Calcium carbonate, cholecalciferol (Vit. D3), croscarmellose sodium, magnesium stearate, FD&C Blue No. 2 Aluminium Lake, FD&C Red No. 40 Aluminium Lake, FD&C Yellow No. 6 Aluminium Lake
Contains sugar (less than 0,1% sucrose)

WHAT CALTRATE 600+D IS USED FOR:

CALTRATE 600+D contain two active substances, calcium and vitamin D.

Calcium is an important constituent of bone and vitamin D helps the absorption of the calcium by the intestine and its deposition in the bones.

It is used:

- In the correction of calcium and vitamin D deficiencies.
- In the combination with osteoporosis treatments where calcium and vitamin D levels are low or where there is a high risk of them being too low.

BEFORE YOU TAKE CALTRATE 600+D:

Do not take CALTRATE 600+D:

- If you are allergic to any of the ingredients.
- If you have an abnormally high level of calcium in the blood and /or excessive loss of calcium in the urine (hypercalciuria).
- If you are suffering from kidney failure.
- If you are suffering from kidney stones or have calcium deposits in your kidneys.
- If you are suffering from an excessive supply of vitamin D (hypervitaminosis D).

Take special care with CALTRATE 600+D:

- If you are taking other supplements. Read the label, since these supplements may contain the same ingredients.
- If you are on long term treatment with CALTRATE 600+D, the quantity of calcium in the blood must be regularly monitored. This is particularly important in the elderly and where treatment is being taken at the same time as cardiac glycosides (e.g. digoxin) or diuretics (water tablets).

Consult a healthcare professional prior to use if:

- you have had kidney stones.
- you are suffering from an immune disorder (sarcoidosis), as the amount of calcium in your blood and urine must be checked.
- you are taking any other medicines containing vitamin D or calcium. This may increase the level of calcium in your blood too much which can cause side effects.

Taking CALTRATE 600+D with food and drink:

In the two hours before taking CALTRATE 600+D, you should avoid eating foods containing oxalic acid (e.g. spinach and rhubarb) or phytic acid (e.g. wholegrain cereals), which can reduce calcium absorption.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking CALTRATE 600+D.

CALTRATE 600+D can be used during pregnancy and lactation.

During pregnancy the total daily intake of calcium should not be higher than 1500 mg and the daily intake of vitamin D not higher than 600 IU.

As calcium and vitamin D passes into breast milk you have to check with your doctor first if your infant receives any other products containing vitamin D.

Driving and using machinery:

CALTRATE 600+D does not contain any ingredients causing drowsiness, so CALTRATE 600+D should not affect the ability to drive or operate machinery.

Important information about some of the ingredients of CALTRATE 600+D:

Gelatin free, Lactose free, Preservatives free
Potential allergens: no known allergens

Taking other medicines with CALTRATE 600+D:

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

In particular,

- Thiazide diuretics (medicines used to treat high blood pressure), as they may increase the amount of calcium in your blood.
- Oral steroids, as they may reduce the amount of calcium in your blood.
- Cardiac glycosides (medicines used to treat heart problems), as they may cause more side effects if you take too much calcium.
- Tetracycline antibiotics, as the amount absorbed may be reduced. They should be taken at least 2 hours before, or 4 – 6 hours after CALTRATE 600+D.
- Bisphosphonates (a treatment for bone conditions), fluoride or fluoroquinolones (a type of antibiotic), as the amount absorbed may be reduced. They should be taken at least 3 hours before or after CALTRATE 600+D.
- Other medicines containing calcium or vitamin D while you are taking CALTRATE 600+D. this may increase the level of calcium in your blood.

HOW TO TAKE CALTRATE 600+D:

Always take CALTRATE 600+D as your doctor has told you. You should check with your doctor if you are not sure.

The usual dose is 1 tablet daily for adults and elderly.

You should take the tablet with a glass of water (200 ml). If you have difficulties in swallowing the tablet, you can halve the tablet. Do not exceed the recommended dose.

If you take more CALTRATE 600+D 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.

If you experience any of the symptoms of overdose, stop taking CALTRATE 600+D and immediately contact your doctor.

Symptoms of overdose may include: anorexia, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, bone pain and kidney stones.

If you forget to take CALTRATE 600+D:

Do not take a double dose to compensate for a forgotten dose.

POSSIBLE SIDE EFFECTS:

CALTRATE 600+D can have side effects.

Not all side effects reported for CALTRATE 600+D are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CALTRATE 600+D, please consult your healthcare provider for advice.



Tell your doctor if you notice any of the following: Constipation, flatulence, feeling sick (nausea), abdominal pain, diarrhoea, itching, skin rashes and urticaria.

Other side effects: kidney stones.

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

STORING AND DISPOSAL OF CALTRATE 600+D:

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

Store all medicines out of reach of children.

Keep the container firmly closed.

Do not store in a bathroom.

Do not use after the expiry date stated on the bottle label and carton.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF CALTRATE 600+D:

CALTRATE 600+D is packed in white plastic bottles and caps in counts of 30 or 60 tablets into a cardboard carton, with an insert.

This container is sealed with a tamper-evident foil for your safety.

Do not use if the foil is broken.

IDENTIFICATION AND DESCRIPTION OF CALTRATE 600+D:

CALTRATE 600+D is a rose coloured, oval shaped, film coated tablet, engraved with "600" on the left and "D" on the right of the bisect line and "Caltrate" on the opposite side.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF REGISTRATION HOLDER:

GlaxoSmithKline
Consumer Healthcare South Africa (Pty) Ltd.
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7460

Tel: 0800 118 274/ +27 11 745 6001

Manufacturer: PF Consumer Healthcare Canada ULC.
1025 Marcel-Laurin Boulevard
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1 June 2018

For more information, visit www.caltrate.co.za



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ÉPREUVE # / PROOF #	DMENSIONS	FINITION / FINISH	DATE	<input type="checkbox"/> APPROVED <input type="checkbox"/> NEW PROOF REQUIRED	
02	300mm x 274mm	Folded 150mm x 36mm	6 MAY, 2020		
# PRODUIT / PRODUCT #	MATÉRIEL / MATERIAL		REFERENCE		
PAA144641	PHARMA OPAQUE 30M			DATE	AUTHORIZED SIGNATURE
<div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">  <p>BLACK</p> </div> <div style="text-align: center;"> <p>SupremeX</p> </div> </div>					
NOTES: Grain parallel 274mm					



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**CALTRATE 600+D
PASIËNTINLIGTINGSVOUBILJET**

34.12 Kategorie D – Aanvullende medisyne – Gesondheidsaanvulling

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of bedoelde gebruik geëvalueer nie.

SKEDULERINGSSTATUS: S0**EIENDOMSNAAM EN DOSEERVORM:**
CALTRATE® 600+D (Tablette)**Lees die hele voubiljet aandagtig deur omdat dit belangrike inligting vir u bevat.**

CALTRATE 600+D is sonder 'n doktersvoorskrif beskikbaar vir u om as 'n gesondheidsaanvulling te gebruik. Nietemin moet u steeds CALTRATE 600+D met sorg gebruik, sodat u die beste resultate daarvan kan verkry.

- Hou hierdie voubiljet. U sal dit moontlik weer moet lees.
- Moenie CALTRATE 600+D met enigiemand anders deel nie.
- Vra u apteker as u meer inligting of advies benodig.
- U moet 'n dokter spreek as u kommerwekkende simptome ervaar.

WAT CALTRATE 600+D BEVAT:

Die aktiewe stowwe is soos volg:

Elke CALTRATE 600+D-tablet bevat	Per tablet
Kalsium*	600 mg
Vitamien D	400 IE

* 1 500 mg kalsiumkarbonaat wat gelykwaardig is aan 600 mg elementêre kalsium.

Die volledige lys bestanddele is: kalsiumkarbonaat, cholekalsiferol (Vit. D3), kruiskarmellose natrium, magnesiumstearaat, FD&C blou nommer 2 aluminiumlak; FD&C rooi nommer 40 aluminiumlak; FD&C geel nommer 6 aluminiumlak
Bevat Suiker (minder as 0, 1 % sukrose)**WAARVOOR CALTRATE 600+D GEBRUIK WORD:**
CALTRATE 600+D bevat twee aktiewe stowwe – kalsium en vitamien D.

Kalsium is 'n belangrike bestanddeel van been en vitamien D help dat kalsium in die ingewande opgeneem en in die been afgeset word.

Dit word gebruik:

- vir die regstelling van kalsium- en vitamien D-tekorte.
- in kombinasie met osteoporose-behandelings waar kalsium- en vitamien D-vlakke laag is, of waar daar 'n hoë risiko bestaan dat die vlakke te laag is.

VOORDAT U CALTRATE 600+D NEEM:**Moenie CALTRATE 600+D neem:**

- as u allergies is vir enige van die bestanddele.
- as u 'n abnormaal hoë vlak van kalsium in die bloed het en/of oormatige verlies aan kalsium in die urien (hiperkalsiurie) het.
- as u aan nierversaking ly.

- as u nierstene het of kalsiumneerslae in u niere het.
- as u 'n oormatige hoeveelheid vitamien D het (hipervitaminose D).

Neem spesiale sorg met CALTRATE 600+D:

- As u ander aanvullings gebruik. Lees die etiket aangesien hierdie aanvullings moontlik dieselfde bestanddele kan bevat.
- As u in die langtermyn met CALTRATE 600+D behandel word, moet die hoeveelheid kalsium in u bloed gereeld gemonitor word. Dit is veral belangrik by bejaardes en waar behandeling saam met kardiaal glikosiede (bv. digoksien) of diuretika (waterpille) gebruik word.

Spreek 'n gesondheidsorgdeskundige voor gebruik, in die volgende gevalle:

- U het nierstene gehad.
- U ly aan 'n immuunversteuring (sarkoïedose) aangesien die hoeveelheid kalsium in u bloed en urien gekontroleer moet word.
- U gebruik enige ander medisyne wat vitamien D of kalsium bevat. Dit kan moontlik die vlak van kalsium in u bloed te veel verhoog wat nuwe-effekte kan veroorsaak.

Neem van CALTRATE 600+D saam met kos en drinkgoed:

U moet twee uur voordat u CALTRATE 600+D neem kos vermy wat oksaalsuur (soos spinasie of rabarber) of fitiensuur (soos heelgraanprodukte) bevat wat die absorpsie van kalsium kan verminder.

Swangerskap en borsvoeding:

As u swanger is of u baba borsvoed, moet u as seblief u gesondheidsorgverskaffer raadpleeg vir advies alvorens u CALTRATE 600+D gebruik.

CALTRATE 600+D kan wel gedurende swangerskap en borsvoeding gebruik word.

Gedurende swangerskap moet die totale daaglikse inname van kalsium nie 1 500 mg oorskry nie, en die daaglikse inname van vitamien D moenie 600 IE oorskry nie.

Aangesien kalsium en vitamien D in borsmelk uitgeskei word, moet u eers by u dokter seker maak as u baba enige ander produkte ontvang wat ook vitamien D bevat.

Bestuur van 'n voertuig en die gebruik van masjinerie:

CALTRATE 600+D bevat geen bestanddele wat lomerigheid veroorsaak nie. CALTRATE 600+D behoort dus nie die vermoë te affekteer om te bestuur of masjinerie te gebruik nie.

Belangrike inligting oor van die bestanddele in CALTRATE 600+D:Gelatien vry, Laktose vry, Preserveermiddels vry
Potensiële allergene: geen bekende allergene nie.**Neem van ander medisyne saam met CALTRATE 600+D:**

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in).

Veral die volgende:

- Tiasied-diuretika (medisyne wat gebruik word om hoë bloeddruk mee te behandel), aangesien dit die hoeveelheid kalsium in die bloed kan verhoog.
- Mondelike steroïedmedikasie, aangesien dit die hoeveelheid kalsium in die bloed kan verminder.
- Kardiale glikosiede (medisyne om hartprobleme mee te behandel), aangesien

dit meer nuwe-effekte kan veroorsaak as u te veel kalsium inneem.

- Tetrasiklien-antibiotika, aangesien die hoeveelheid wat geabsorbeer word, verminder kan wees. Dit moet minstens 2 uur voor of 4–6 uur ná CALTRATE 600+D geneem word.
- Bisfosfonate (behandeling vir gebeentetoestande), fluoried of fluoorkinolone ('n soort antibiotikum), aangesien die hoeveelheid wat geabsorbeer word, verminder kan wees. Dit moet minstens 3 uur voor of ná CALTRATE 600+D geneem word.
- Ander medisyne wat kalsium of vitamien D bevat terwyl u CALTRATE 600+D neem, aangesien dit moontlik die vlak van kalsium in die bloed kan verhoog.

HOE OM CALTRATE 600+D TE NEEM:

Neem altyd CALTRATE 600+D presies soos u deur u dokter aangesê is. U moet dit met u dokter uitklaar as u nie seker is nie.

Die gewone dosis is 1 tablet daagliks vir volwassenes en bejaardes.

U moet die tablet met 'n glas water (200 ml) afsluk. As u sukkel om die tablet afgesluk te kry, kan u die tablet in die helfte breek. Moenie die aanbevole dosis oorskry nie.

As u meer CALTRATE 600+D neem as wat u behoort:

Ingeval van 'n oordosering, raadpleeg u dokter of apteker. As nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As u enige van die simptome van oordosering ervaar, hou op om CALTRATE 600+D te neem en kontak onmiddellik u dokter.

Simptome van oordosering kan moontlik insluit anoreksie, oormatige dors, naarheid, braking, hardlywigheid, buikpyn, spierswakheid, vermoeidheid, gebeentepyn en nierstene.

As u vergeet om u CALTRATE 600+D te neem:

Moenie 'n dubbeldosis neem om vir 'n vergete dosis in te haal nie.

MOONTLIKE NUWE-EFFEKTE:

CALTRATE 600+D kan nuwe-effekte veroorsaak.

Nie alle nuwe-effekte wat vir CALTRATE 600+D aangemeld is, word by hierdie voubiljet ingesluit nie. Sou u algemene gesondheid verswak, of as u enige ongewone effekte ontwikkel terwyl u CALTRATE 600+D neem, moet u u dokter of gesondheidsorgverskaffer vir advies nader.

Sê vir u dokter as u enige van die volgende opmerk:

Hardlywigheid, winderigheid, naarheid, buikpyn, diarree, 'n gejeuk, veluitslag en urtikarie. Ander nuwe-effekte: nierstene.

As u enige nuwe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, moet u asseblief u dokter of apteker in kennis stel.

BERGING EN WEGDOENING VAN CALTRATE 600+D:

Bewaar teen of benede 25 °C op 'n koel, droë plek.

Bewaar alle medisyne buite die bereik van kinders. Hou die houer dig toe.

Moenie in die badkamer berg nie.

Moenie gebruik ná die vervaldatum op die bottel se etiket en dié op die kartonhouer verstryk het nie. Gee alle ongebruikte medisyne aan u apteker terug.

Moenie met ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) mee wegdoen nie.

AANBIEDING VAN CALTRATE 600+D:

CALTRATE 600+D word verpak in wit plastiekbottels met doppies en bevat 30 of 60 tablette wat in 'n kartonhouer verpak word waarin 'n voubiljet geplaas is.

Hierdie houer word vir u veiligheid met 'n peuteeraanduidende foeliebedekking geseël. Moenie gebruik as die foeliebedekking stukkend is nie.

IDENTIFIKASIE EN BESKRYWING VAN CALTRATE 600+D:

CALTRATE 600+D is 'n rooskleurige, ovaalvormige, filmbedekte tablet wat aan die linkerkant van die keeplyn met "600" gegraveer is en met "D" aan die regterkant. Aan die teenoorgestelde kant van die tablet is die woord "CALTRATE" gegraveer.

NAAM, BESIGHEIDSADRES EN TELEFONNOMMER VAN DIE REGISTRASIEHOUER:GlaxoSmithKline
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Manufacturer: PF Consumer Healthcare Canada ULC.
1025 Marcel-Laurin Boulevard
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1 Junie 2018

Besoek www.caltrate.co.za vir meer inligting.

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# PRODUIT / PRODUCT #	MATÉRIEL / MATERIAL		REFERENCE	DATE	AUTHORIZED SIGNATURE
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