PAA147585

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CALTRATE PLUS CHEWABLES
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: S0

PROPRIETARY NAME AND DOSAGE FORM:
CALTRATE® PLUS CHEWABLES
Chewable tablets

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CALTRATE PLUS CHEWABLES 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® PLUS CHEWABLES CONTAINS:
The active substances are:

Each CALTRATE® PLUS CHEWABLE tablet contains	Per tablet
Calcium*	600 mg
Vitamin D3	500 IU
Magnesium	40 mg
Zinc	7,5 mg
Copper	0,25 mg
Manganese	1,8 mg
Boron	70 µg

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

Minerals added as: calcium carbonate, copper sulfate, magnesium oxide, magnesium borate, manganese sulfate and zinc oxide.

Other ingredients are: citric acid anhydrous, flavour taste modifier natural, magnesium stearate, sucralose, xylitab 100, flavour orange, flavour fruit punch, flavour wild cherry, FD&C Yellow #6, Lake blend purple LB-562 and FD&C Red 40.

Contains sugar 7, 34 mg per tablet (sucrose, dextrose and fructose).

Contains sweetener 665 mg per tablet (xylitol).

WHAT CALTRATE PLUS CHEWABLES IS USED FOR:
CALTRATE PLUS CHEWABLES is a health supplement containing calcium, vitamin D3 and minerals.

Calcium: for the development and maintenance of bone strength.
Vitamin D3: to help in the absorption and use of calcium and phosphorus by bones.

Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis.

Minerals also present in CALTRATE PLUS CHEWABLES are:

Magnesium: contributes to the development and maintenance of bones and teeth, tissue formation and is a factor in the maintenance of good health.
Zinc: is essential for the formation of protein and collagen. Up to 30 % of the body's supply of zinc is held in the skeletal tissue.
Copper: is a co-factor for several enzymatic reactions, including that responsible for formation of collagen, a component of bone tissue.
Manganese: plays an important role for formation of bones and cartilages, and is an enzyme co-factor for collagen formation.
Boron: assists in regulating calcium absorption.

BEFORE YOU TAKE CALTRATE PLUS CHEWABLES:
Do not take CALTRATE PLUS CHEWABLES:
- 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 D3 (hypervitaminosis D).
- If your parathyroid glands have increased function.
- If you suffer from sarcoidosis (an immune disorder).

Take special care with CALTRATE PLUS CHEWABLES:
- 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 PLUS CHEWABLES, 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 taking any other medicines containing vitamin D3 or calcium. This may increase the level of calcium in your blood too much which can cause side effects.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking CALTRATE PLUS CHEWABLES.

CALTRATE PLUS CHEWABLES 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 D3 not higher than 600 IU.

As calcium and vitamin D3 passes into breast milk you have to check with your doctor first if your infant receives any other products containing vitamin D3.

Driving and using machinery:
CALTRATE PLUS CHEWABLES does not contain any ingredients causing drowsiness, so CALTRATE PLUS CHEWABLES should not affect the ability to drive or operate machinery.

Important information about some of the ingredients of CALTRATE PLUS CHEWABLES:
Lactose free. Preservatives free. Gelatin free

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking CALTRATE PLUS CHEWABLES.

CALTRATE PLUS CHEWABLES contains sucrose (7, 34 mg per tablet) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

CALTRATE PLUS CHEWABLES contains xylitol (665 mg per tablet). If you have been told that you have intolerance to some sugars, you should not take CALTRATE PLUS CHEWABLES.

Taking other medicines with CALTRATE® PLUS CHEWABLES:
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 PLUS CHEWABLES.
- 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 PLUS CHEWABLES.
- Other medicines containing calcium or vitamin D3 while you are taking CALTRATE PLUS CHEWABLES, as this may increase the level of calcium in your blood.

Taking CALTRATE® PLUS CHEWABLES with food and drink:
- In the two hours before taking CALTRATE PLUS CHEWABLES, 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.

HOW TO TAKE CALTRATE PLUS CHEWABLES:
Always take CALTRATE PLUS CHEWABLES 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. Chew the tablet completely before swallowing. Do not exceed the recommended dose.

If you take more CALTRATE PLUS CHEWABLES 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 PLUS CHEWABLES 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 PLUS CHEWABLES:
Do not take a double dose to make up for the forgotten dose.

POSSIBLE SIDE EFFECTS:
CALTRATE PLUS CHEWABLES can have side effects.

Not all side effects reported for CALTRATE PLUS CHEWABLES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CALTRATE PLUS CHEWABLES, 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.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORAGE AND DISPOSAL OF CALTRATE PLUS CHEWABLES:
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 PLUS CHEWABLES:
CALTRATE PLUS CHEWABLES 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 PLUS CHEWABLES:
CALTRATE PLUS CHEWABLES tablets have 3 assorted flavours.

Orange flavour – Orange round shaped tablets.
Cherry flavour – Red round shaped tablets.
Fruit punch flavour – Purple round shaped tablets.

All of the tablets are embossed with "Caltrate" over "PLUS" on one side and the other side "1".

NAME BUSINESS ADDRESS AND TELEPHONE NUMBER OF REGISTRATION HOLDER:
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1 June 2018

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

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PAA147485	Pharma Opaque 30 lbs	

DATE	AUTHORIZED SIGNATURE

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DIELINE

NOTES: Grain: parallel 274mm

SupremeX

PAA147585

CALTRATE PLUS CHEWABLES
PASIËNTINLIGTINGSVOUBILJET

34.12 - Kategorie D: Aanvullende medisyne – Gesondheidsaanvulling

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

SKEDULERINGSTATUS: S0

EIENDOMSNAAM EN DOSEERVORM:
CALTRATE® PLUS CHEWABLES
KOUBARE tablette

Lees die hele voubiljet aandagtig deur omdat dit belangrike inligting vir u bevat.

CALTRATE PLUS CHEWABLES is sonder ’n doktersvoorskrif beskikbaar vir u om as ’n gesondheidsaanvulling te gebruik. Nietemin moet u steeds CALTRATE PLUS CHEWABLES met sorg gebruik, sodat u die beste resultate daarvan kan verkry.

- Hou hierdie voubiljet. U sal dit moontlik weer moet lees.
- Moenie CALTRATE PLUS CHEWABLES 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.

CALTRATE PLUS CHEWABLES BEVAT DIE VOLGENDE:
Die aktiewe stowwe is soos volg:

Elke CALTRATE® PLUS CHEWABLES tablet bevat	Per tablet
Kalsium*	600 mg
Vitamien D3	500 IE
Magnesium	40 mg
Sink	7,5 mg
Koper	0,25 mg
Mangaan	1,8 mg
Boor	70 µg

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

Minerale is bygevoeg as: kalsiumkarbonaat, kopersulfaat, magnesiumboraat, magnesiumoksied, mangaansulfaat en sinkoksied.

Ander bestanddele is: anhidriese sitroensuur, natuurlike geur-en-smaak-wysiger, geure: vrugtepons, lemoen, wilde kersie; magnesiumstearaat, sukralose, xilitab 100, FD&C-geel nommer 6, vermengde LB- 562-pers-lak en FD&C-rooi 40.

Bevat suiker 7, 34 mg per tablet (sukrose, dekstrose en fructose).

Bevat versoeter 665 mg per tablet (xylitol).

WAARVOOR CALTRATE PLUS CHEWABLES GEBRUIK WORD:
CALTRATE PLUS CHEWABLES is ’n gesondheidsaanvulling wat kalsium, vitamien D3 en minerale bevat.

Kalsium: vir die ontwikkeling en handhawing van sterk been.
Vitamien D3: om te help met die absorpsie en gebruik van kalsium en fosfor deur been.

Kalsiuminname, wanneer dit met voldoende vitamien D, ’n gesonde dieet en gereelde oefening gekombineer word, kan moontlik die risiko vir osteoporose verminder.

Minerale wat ook in CALTRATE PLUS CHEWABLES voorkom, is:

Magnesium: dra by tot die ontwikkeling en handhawing van been en tande, weefselvorming en is ’n faktor in die handhawing van goeie gesonheid.
Sink: is noodsaaklik vir die vorming van proteïen en kollageen. Tot 30% van die liggaam se voorraad van sink word in skeletweefsel geberg.
Koper: is ’n kofaktor vir verskeie ensiemreaksies, insluitend dié wat vir die vorming van kollageen (’n komponent van beenweefsel) verantwoordelik is.
Mangaan: speel ’n belangrike rol in die vorming van been en kraakbeen en is ’n ensiemkofaktor vir kollageenvorming.
Boor: help om kalsiumabsorpsie te reguleer.

VOORDAT U CALTRATE PLUS CHEWABLES NEEM:
Moenie CALTRATE PLUS CHEWABLES neem nie as u:
- allergies is vir enige van die bestanddele.
- ’n abnormaal hoë vlak van kalsium in die bloed het en/of oormatige verlies aan kalsium in die urien (hiperkalsiurie) het.
- aan nierversaking ly.
- nierstene het of kalsiumneerslae in u niere het.
- ’n oormatige hoeveelheid vitamien D het (hipervitaminose D).
- paratiroïedkliere se funksie verhoog is.
- aan sarkoïedose (’n immuunversteuring) ly.

Neem spesiale sorg met CALTRATE PLUS CHEWABLES:
- as u ander aanvullings gebruik. Lees die etiket aangesien hierdie aanvullings moontlik dieselfde bestanddele kan bevat.
- as u in die langtermyn met CALTRATE PLUS CHEWABLES behandel word, moet die hoeveelheid kalsium in u bloed gereeld gemonitor word. Dit is veral belangrik by bejaardes en waar behandeling saam met kardiale glikosiede (bv. digoksien) of diuretika (waterpille) gebruik word.

Spreek ’n gesondheidsorgdeskundige voor gebruik, in die volgende gevalle:
- U het nierstene gehad.
- 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 newe-effekte kan veroorsaak.

Swangerskap en borsvoeding:
As u swanger is of u baba borsvoed, moet u asseblief u gesondheidsorgverskaffer raadpleeg vir advies alvorens u CALTRATE PLUS CHEWABLES gebruik.

CALTRATE PLUS CHEWABLES 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 D3 moenie 600 IE oorskry nie.

Aangesien kalsium en vitamien D3 in borsmelk uitgeskei word, moet u eers by u dokter seker maak as u baba enige ander produkte ontvang wat ook vitamien D3 bevat.

Bestuur van ’n voertuig en die gebruik van masjinerie:
CALTRATE PLUS CHEWABLES bevat geen bestanddele wat lomerigheid veroorsaak nie. CALTRATE PLUS CHEWABLES behoort dus nie die vermoë te affekteer om te bestuur of masjinerie te gebruik nie.

Belangrike inligting oor ván die bestanddele in CALTRATE PLUS CHEWABLES:
Laktose vry. Preserveermiddels vry. Gelatien vry.

As u dokter vir u gesê het dat u ’n intoleransie vir sekere suikers het, moet u u dokter kontak voordat u CALTRATE PLUS CHEWABLES neem.

CALTRATE PLUS CHEWABLES bevat sukrose (7, 34 mg per tablet) wat moontlik ’n effek op bloedsuikerbeheer kan hê as u aan diabetes mellitus ly.

CALTRATE PLUS CHEWABLES bevat xylitol (665 mg per tablet). As u dokter vir u gesê het dat u ’n intoleransie vir sekere suikers het, jy moet nie vat nie CALTRATE PLUS CHEWABLES.

Die neem van ander medisyne saam met CALTRATE PLUS CHEWABLES:
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.
- Mondelikse steroïedmedikasie, aangesien dit die hoeveelheid kalsium in die bloed kan verminder.
- Kardiale glikosiede (medisyne om hartprobleme mee te behandel), aangesien dit meer newe-effekte kan veroorsaak as u te veel kalsium innee.
- Tetrasiklien-antibiotika, aangesien die hoeveelheid wat geabsorbeer word, verminder kan wees. Dit moet minstens 2 uur vóór of 4-6 uur ná CALTRATE PLUS CHEWABLES 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 vóór of ná CALTRATE PLUS CHEWABLES geneem word.
- Ander medisyne wat kalsium of vitamien D3 bevat terwyl u CALTRATE PLUS CHEWABLES neem, aangesien dit moontlik die vlak van kalsium in die bloed kan verhoog.

Neem van CALTRATE PLUS CHEWABLES saam met kos en drinkgoed:
- U moet twee uur voordat u CALTRATE PLUS CHEWABLES neem kos vermy wat oksaalsuur (soos spinasie of rabarber) of fitiensuur (soos heelgraanprodukte) bevat, wat die absorpsie van kalsium kan verminder.

HOE OM CALTRATE PLUS CHEWABLES TE NEEM:
Neem altyd CALTRATE PLUS CHEWABLES 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.

Kou die tablet heeltemal voordat u dit afsluk. Moenie die aanbevole dosis oorskry nie.

As u meer CALTRATE PLUS CHEWABLES neem as wat u behoort te neem:
In geval 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 PLUS CHEWABLES 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 PLUS CHEWABLES te neem:
Moenie ’n dubbeldosis neem om ’n vergete dosis in te haal nie.

MOONTLIKE NEWE-EFFEKTE:
CALTRATE PLUS CHEWABLES kan newe-effekte veroorsaak.

Nie al die newe-effekte wat vir CALTRATE PLUS CHEWABLES aangemeld is, word by hierdie voubiljet ingesluit nie. Sou u algemene gesondheid verswak, of as u enige ongewone effekte ontwikkel terwyl u CALTRATE PLUS CHEWABLES neem, moet u u 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.

As u enige newe-effekte opmerk wat nie in hierdie voubiljet uiteengesit is nie, moet u asseblief u dokter of apteker in kennis stel.

BERGING EN WEGDOENING VAN CALTRATE PLUS CHEWABLES:
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 PLUS CHEWABLES:
CALTRATE PLUS CHEWABLES 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 peuteraanduidende foeliebedekking geseël. Moenie gebruik as die foeliebedekking stukkend is nie.

IDENTIFIKASIE EN BESKRYWING VAN CALTRATE PLUS CHEWABLES:
CALTRATE PLUS CHEWABLES tablette het 3 verskillende soorte geure.

Lemoengeur – oranje ronde tablette.
Kersiegeur – rooi ronde tablette.
Vrugteponsgeur – pers ronde tablette.

Al die tablette is aan die een kant met die woord “Caltrate” oor die woord “PLUS”, en met “1” aan die ander kant gebosseleer.

NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE REGISTRASIEHOUER:
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Besoek **www.caltrate.co.za** vir meer inligting.

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01	300mm x 274mm	Folded 150mm x 36mm	20 MAY, 2020

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PAA147485	Pharma Opaque 30 lbs	

DATE	AUTHORIZED SIGNATURE

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DIELINE

NOTES: Grain: parallel 274mm

SupremeX