

BRAINCHILD CALCIUM MAGNESIUM

CHEWABLE TABLETS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
BrainChild Calcium Magnesium (Chewable tablets)

Read all of this leaflet carefully because it contains important information for you
BrainChild Calcium Magnesium Chewable tablets are available without a doctor's prescription. Nevertheless you still need to use the product carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or healthcare practitioner if you need more information or advice.
- BrainChild Calcium Magnesium is a health supplement for children. Health supplements are intended only to complement health or supplement the diet.

1. WHAT BRAINCHILD CALCIUM MAGNESIUM CONTAINS

The active ingredients in BrainChild Calcium Magnesium are Calcium (as Calcium carbonate) 125 mg and Magnesium (as Magnesium oxide) 50 mg. The other ingredients are dextrates, glucose, magnesium stearate, mannitol, orange colouring, sorbitol, tangerine flavouring.
Contains sugar and sugar alcohols (glucose 312 mg, mannitol 25 mg, sorbitol 40 mg). Lactose free.

2. WHAT BRAINCHILD CALCIUM MAGNESIUM IS USED FOR

BrainChild Calcium Magnesium chewable tablets are a fruity citrus-flavoured calcium and magnesium supplement for children. Calcium contributes to the development and maintenance of bones and teeth and contributes to tissue formation. Calcium also assists with normal muscle function. Magnesium aids the absorption of calcium. BrainChild Calcium Magnesium is specially formulated to be lactose free to provide a convenient supplement where dietary intake of dairy products and other calcium sources is limited.

3. BEFORE YOU TAKE BRAINCHILD CALCIUM MAGNESIUM

Do not take BrainChild Calcium Magnesium

- If your child has a tendency to develop kidney stones, please consult your doctor or healthcare practitioner before using a calcium supplement.
- If you are hypersensitive (allergic) or intolerant to any of the active ingredients or other ingredients in BrainChild Calcium Magnesium.

Take special care with BrainChild Calcium Magnesium:

- If your child has been diagnosed with hypercalcaemia or any kidney disease, please consult your doctor or healthcare practitioner before using a calcium or magnesium supplement.
- If your child experiences an allergic reaction after taking BrainChild Calcium Magnesium, discontinue use and consult your healthcare practitioner.
- Calcium or magnesium may reduce the absorption of some other medications, therefore take BrainChild Calcium Magnesium 2 - 3 hours away from other medicines.
- If you want to substitute existing medical treatment, please consult your doctor or healthcare practitioner before doing so.

Taking BrainChild Calcium Magnesium with food and drink
BrainChild Calcium Magnesium may be taken with food.

Driving and using machinery

BrainChild Calcium Magnesium does not interfere with a person's ability to drive or use machinery.

Important information about some of the ingredients

If you are unsure of any of the ingredients or if your child is on medication or has a pre-existing condition, speak to

your healthcare practitioner before using this supplement. Contains sugar (glucose) and sugar alcohols (mannitol, sorbitol) which may have an effect on the glycaemic control of patients with diabetes mellitus. If you have been told that your child has an intolerance to some sugars, do not use BrainChild Calcium Magnesium.

Using other medicines with BrainChild Calcium Magnesium

Always tell your healthcare practitioner if you are taking other medicines. (This includes complementary or traditional medicines.) If your child is taking other supplements which contain calcium or magnesium, it may be possible to exceed the recommended daily doses of these minerals. If your child is taking special or prescribed medication or has a pre-existing condition, consult your healthcare practitioner before using this supplement. Calcium or magnesium may reduce the absorption of some other medications, therefore take BrainChild Calcium Magnesium 2 - 3 hours away from other medicines.

4. HOW TO TAKE BRAINCHILD CALCIUM MAGNESIUM

Do not share medicines prescribed for you with any other person. Always check with your pharmacist or healthcare practitioner if you are unsure how to take this health supplement.

The usual dosage is:

Children 3 years: Chew 1 tablet daily.
Children 4 - 12 years: Chew 1 tablet twice daily.
The dosage may be adapted by your healthcare practitioner.

If you take more BrainChild Calcium Magnesium than you should

High doses of calcium may lead to hypercalcaemia with symptoms including thirst, frequent urination, anorexia, constipation, muscle weakness, fatigue and exhaustion. In severe cases, symptoms include nausea, vomiting and an irregular heartbeat. High doses of Magnesium may cause diarrhoea. If a side effect is experienced following an overdose, discontinue use and consult your healthcare practitioner or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of BrainChild Calcium Magnesium

Do not take a double dose to make up for a missed dose.

5. POSSIBLE SIDE EFFECTS

Side effects associated with calcium and magnesium supplementation include gastrointestinal irritation and watery diarrhoea. Should your general health worsen or if you experience any untoward effects while taking this health supplement, please consult your healthcare practitioner or pharmacist for advice.

6. STORING AND DISPOSING OF BRAINCHILD CALCIUM MAGNESIUM

Store at or below 25 °C in a cool, dry place protected from light and moisture. Keep the container tightly closed. Do not store in a bathroom. **Store all medicines out of the reach of children.** Return all un-used medicines to your pharmacist.

7. PRESENTATION OF BRAINCHILD CALCIUM MAGNESIUM

BrainChild Calcium Magnesium tablets are available as 60 chewable tablets in a white, plastic bottle with screw-on cap and pressure seal.

8. IDENTIFICATION

BrainChild Calcium Magnesium chewable tablets are round, orange tablets with pale spots, citrus aroma and slightly tangy, sweet flavour. Minor variations in colour and flavour are possible.

9. REFERENCE NUMBER

To be provided.

10. NAME AND ADDRESS OF THE APPLICANT

CoMED Health (Pty) Ltd., 313 Kuit Street, Waltho, Pretoria, 0184. Tel: 012 813 9400.
www.comedhealth.co.za

11. DATE OF PUBLICATION

July 2019

12. COMPLEMENTARY MEDICINE

Health supplement

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

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BRAINCHILD CALCIUM MAGNESIUM

KOU TABLETTE

PASIËNT INLIGTINGSBLAD

SKEDULERING STATUS S0

HANDELSNAAM, STERKTE EN DOSEERVORM
BrainChild Calcium Magnesium (Kou tablette)

Lees hierdie inligtingsblad sorgvuldig deur, want dit bevat belangrike inligting vir jou
BrainChild Calcium Magnesium is beskikbaar sonder 'n dokter se voorskrif. Tog moet BrainChild Calcium Magnesium noukeurig gebruik word om die beste resultate daaruit te kry.

- Bewaar hierdie inligtingsblad veilig. Dit mag nodig wees om dit weer te lees.
- Vra jou apteker of gesondheidspraktisyn as jy meer inligting of advies benodig.
- BrainChild Calcium Magnesium is 'n gesondheidsaanvulling vir kinders. Gesondheidsaanvullings is slegs bedoel om of die gesondheid of die dieet aan te vul.

1. WAT BRAINCHILD CALCIUM MAGNESIUM BEVAT

Die aktiewe bestanddele in BrainChild Calcium Magnesium is Kalsium (as Kalsiumkarbonaat) 125 mg en Magnesium (as Magnesiumoksied) 50 mg. Die ander bestanddele is dekstrate, glukose, magnesium stearaat, mannitol, sorbitol, lemoen kleursel, naartjie geursel.

Bevat suiker en suikeralkohol (glukose 329 mg, mannitol 25 mg, sorbitol 40 mg). Laktose vry.

2. WAARVOOR BRAINCHILD CALCIUM MAGNESIUM GEBRUIK WORD

BrainChild Calcium Magnesium kou tablette is 'n vrugtige sitrus-geurende kalsium en magnesium aanvulling vir kinders. Kalsium dra by tot die ontwikkeling en instandhouding van bene en tande en dra by tot weefselformasie. Kalsium help ook met normale spierfunksie. Magnesium help met die absorpsie van kalsium. BrainChild Calcium Magnesium is spesiaal geformuleer om laktose vry te wees om 'n gerieflike aanvulling te verskaf waar die inname van suiwelprodukte en ander kalsiumbronne beperk is.

3. VOORDAT JY BRAINCHILD CALCIUM MAGNESIUM GEBRUIK

Moet nie BrainChild Calcium Magnesium neem as

- Jou kind 'n neiging het om nierstene te ontwikkel, raadpleeg jou dokter of gesondheidspraktisyn voor jy 'n kalsium aanvulling gebruik.
- Jou kind hipersensitief (allergies) is teenoor enige van die aktiewe bestanddele of ander bestanddele van BrainChild Calcium Magnesium of dit nie kan verdra nie.

Wees veral versigtig met BrainChild Calcium Magnesium:

- Indien jou kind met hiperkalkemie of enige niersiekte gediagnoseer is, raadpleeg jou dokter of gesondheidspraktisyn voordat jy 'n kalsium- of magnesiumaanvulling gebruik.
- Indien jou kind 'n allergiese reaksie ervaar nadat jy BrainChild Calcium Magnesium geneem het, stop dadelik die gebruik daarvan en raadpleeg jou gesondheidspraktisyn.
- Kalsium of magnesium kan die absorpsie van ander medikasie verminder, daarom neem BrainChild Calcium Magnesium 2 - 3 uur voor of na ander medisyne.
- As jy bestaande mediese behandeling wil vervang, raadpleeg jou dokter of gesondheidspraktisyn voordat jy dit doen.

Gebruik van BrainChild Calcium Magnesium saam met voedsel en vloeistowwe
BrainChild Calcium Magnesium mag saam met voedsel en vloeistowwe geneem word.

Die gebruik en bestuur van masjinerie

Die inname van BrainChild Calcium Magnesium beïnvloed nie die mens se vermoë om masjinerie te bestuur en veilig te gebruik nie.

Belangrike inligting oor sommige van die bestanddele

As jy nie seker is van enige van die bestanddele nie, of indien jou kind op medikasie is of 'n vooraf gediagnoseerde toestand het, raadpleeg jou gesondheidspraktisyn voordat jy hierdie aanvulling gebruik. Bevat suiker (glukose) en

suikeralkohol (mannitol, sorbitol) wat 'n uitwerking op die glukemiese beheer van pasiënte met diabetes mellitus kan hê. As jy weet dat jou kind onverdraagsaam is teenoor sommige suikers, moenie BrainChild Calcium Magnesium gebruik nie.

Gebruik van ander medisyne saam met BrainChild Calcium Magnesium

Vertel altyd jou gesondheidspraktisyn as jy ander medisyne gebruik, (dit sluit in komplementêre of tradisionele medisyne). As jou kind ander aanvullings gebruik wat kalsium of magnesium bevat, is dit moontlik om die aanbevole daaglikse dosering van minerale te oorskry. As jou kind spesiale of voorgeskrewe medikasie gebruik of 'n vooraf gediagnoseerde toestand het, raadpleeg jou gesondheidspraktisyn voordat jy hierdie aanvulling gebruik. Kalsium of magnesium kan die absorpsie van ander medikasie verminder, daarom neem BrainChild Calcium Magnesium 2 - 3 uur weg van ander medisyne.

4. HOE OM BRAINCHILD CALCIUM MAGNESIUM TE GEBRUIK

Moenie medisyne wat vir jou kind voorgeskryf is, met enige ander persoon deel nie. Raadpleeg altyd jou apteker of gesondheidspraktisyn indien jy nie seker is hoe om hierdie gesondheidsaanvulling te gebruik nie.

Die gewone dosis is:

Kinders 3 jaar: Kou 1 tablet daaglik.
Kinders 4 - 12 jaar: Kou 1 tablet twee keer per dag.
Die dosis kan deur jou gesondheidspraktisyn aangepas word.

Indien jy meer BrainChild Calcium Magnesium gebruik as wat nodig is

Hoë dosisse kalsium kan lei tot hiperkalsemie met simptome soos dors, gereelde urinering, anoreksie, hardywigheid, spierswakheid, moegheid en uitputting. In ernstige gevalle, simptome sluit in naarheid, braking en 'n onreëlmatige hartklop. Hoë dosisse magnesium kan diarree veroorsaak. Indien jy 'n nuwe-effek ervaar, raadpleeg jou gesondheidspraktisyn of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As jy vergeet om 'n dosis BrainChild Calcium Magnesium te neem

Moet nie 'n dubbeldosis neem om vir 'n oorgeslaande dosis op te maak nie.

5. MOONTLIKE NUWE-EFFEKTE

Nuwe-effekte wat verband hou met kalsium- en magnesiumaanvulling, sluit in gastrointestinale irritasie en waterige diarree. Indien jou algemene gesondheid versleg of indien jy enige nuwe effekte ondervind wanneer jy hierdie gesondheidsaanvulling gebruik, raadpleeg jou gesondheidspraktisyn of apteker vir advies.

6. BERGING EN VERNIETIGING VAN BRAINCHILD CALCIUM MAGNESIUM

Stoor by of benede 25°C in 'n koel, droë plek en beskerm teen lig en vog. Hou die houerdig gesluit. Moenie in 'n badkamer stoor nie. **Bewaar alle medisyne buite bereik van kinders.** Stuur alle ongebruikte medisyne aan jou apteker terug.

7. VOORLEGGING VAN BRAINCHILD CALCIUM MAGNESIUM

BrainChild Calcium Magnesium tablette is beskikbaar as 60 koue tablette in 'n wit HDPE houerdig met 'n skroefprop en 'n sekerheidseël.

8. IDENTIFIKASIE

BrainChild Calcium Magnesium tablette is ronde, oranje tablette met ligte kolletjies, sitrus aroma en effens soet smaak. Geringe variasies in geur en kleur is moontlik.

9. VERWYSINGSNOMMER

Om voorsien te word.

10. NAAM EN ADRES VAN DIE APPLIKANT

CoMED Health (Pty) Ltd., Kuitstraat 313, Waltloo, Pretoria, 0184. Tel: 012 813 9400.
www.comedhealth.co.za

11. DATUM VAN PUBLIKASIE

Julie 2019

12. KOMPLEMENTÊRE MEDISYNE

Gesondheidsaanvulling

Vrywaring: Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir sy kwaliteit, veiligheid of voorgestelde gebruik geëvalueer nie.