PASIËNTINLIGTINGSBLAADJIE
CHILL-OUT GUMMIES®

SKEDULERINGSTATUS: S0

CHILL-OUT GUMMIES®, 3 g, Gommetjies
Magnesium, Duitse kamille, valeriaan, suurlemoenbalsem
Bevat suiker: sukrose 1 g per gommetjie en glukosestroop 1 g per gommetjie
Aanvullende Medisyne: Dissipline-Spesifieke Kombinasieproduk

Hierdie ongeregistreerde medisyne is nie deur die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte (SAHPRA) vir die kwaliteit, veiligheid of beoogde gebruik daarvan geëvalueer nie.

Lees hierdie hele blaadjie sorgvuldig aangesien dit belangrike inligting vir u bevat.
CHILL-OUT GUMMIES is sonder 'n doktersvoorskrif beskikbaar om 'n milde kindersiekte te behandel. Nogtans moet u kind CHILL-OUT GUMMIES steeds versigtig gebruik om die beste resultate daarmee te verkry.
- Hou hierdie blaadjie; u mag nodig kry om dit weer te lees.
- Moenie u kind se CHILL-OUT GUMMIES met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U kind moet u dokter spreek indien sy/haar simptome vererger of nie na 14 dae verbeter nie.

Wat in hierdie blaadjie is

1. Wat CHILL-OUT GUMMIES is en waarvoor dit gebruik word
2. Wat u moet weet voordat u CHILL-OUT GUMMIES vir u kind gee
3. Hoe om CHILL-OUT GUMMIES vir u kind te gee
4. Moontlike newe-effekte
5. Hoe om CHILL-OUT GUMMIES te berg
6. Inhoud van die verpakking en ander inligting

1. Wat CHILL-OUT GUMMIES is en waarvoor dit gebruik word
CHILL-OUT GUMMIES is 'n aanvullende medisyne, dissipline-spesifieke kombinasieproduk wat magnesium, Duitse kamille, valeriaan en suurlemoenbalsem bevat. Dit mag gesonde slaappatrone, slaapduur en slaapkwaliteit ondersteun en mag ook help om stres, rusteloosheid en angstigheid in kinders van 2 tot 12 jaar te verlig.

2. Wat u moet weet voordat u CHILL-OUT GUMMIES vir u kind gee MOENIE CHILL-OUT GUMMIES gee nie
- Indien u kind vir magnesiumsitraat, Duitse kamille (sien **Waarskuwings en voorsorgmaatreëls**), valeriaan, suurlemoenbalsem of vir enige van die ander bestanddele in die formulering allergies (hipersensitief) is (sien **Wat CHILL-OUT GUMMIES bevat**).

Waarskuwings en voorsorgmaatreëls
CHILL-OUT GUMMIES bevat Duitse kamille en u moet dit NIE vir u kind gee indien hy/sy allergies vir kamille is nie (sien **MOENIE CHILL-OUT GUMMIES gee nie**). Dit mag ook 'n allergiese reaksie veroorsaak in individue wat sensitief is vir die *Asteraceae/Compositae-plantfamilie* wat ambrosia, krisante, gousblomme, madeliefies en verskeie ander kruie insluit. Staak gebruik onmiddellik indien u kind enige teken van hipersensitiwiteit/allergie toon, soos 'n veluitslag met of sonder galbulte, koors, fluitende asemhaling of 'n benoude bors of swelling van die gesig, lippe, tong of keel (sien **Moontlike newe-effekte**) en konsulteer u dokter.

Indien u kind met 'n niersiekte gediagnoseer is, moet hy/sy CHILL-OUT GUMMIES slegs onder die toesig van sy/haar behandelende dokter gebruik. Dit bevat magnesium en magnesiumuitskeiding is verlaag in pasiënte met ingekorte nierfunksie.

CHILL-OUT GUMMIES bevat suurlemoenbalsem wat skildklierfunksie mag beïnvloed. Indien u kind met skildklierprobleme gediagnoseer is, moet hy/sy CHILL-OUT GUMMIES slegs onder die toesig van sy/haar behandelende dokter gebruik. U kind se dokter sal hom/haar vir die voortgesette effektiwiteit van sy/haar medisyne monitor en dit mag nodig wees om bloedtoetse vir skildklierfunksie van tyd tot tyd te doen (sien **Ander medisyne en CHILL-OUT GUMMIES**).

Indien u kind vir 'n chirurgiese prosedure geskeduleer is, moet hy/sy ten minste twee weke voor die operasie ophou om CHILL-OUT GUMMIES te neem. Die bestanddele in CHILL-OUT GUMMIES mag 'n interaksie hê met geneesmiddels wat algemeen voor, gedurende en na chirurgie gebruik word.

Ander medisyne en CHILL-OUT GUMMIES
Lig altyd u gesondheidsorgverskaffer in indien u kind enige ander medisyne neem. (Dit sluit alle aanvullende of tradisionele geneesmiddels in.)

Indien u kind behandeling met antidepressante, kalmeerpille of slaappille kry, is dit die beste om die gebruik van CHILL-OUT GUMMIES te vermy, want Duitse kamille, valeriaan en suurlemoenbalsem het ook kalmerende eienskappe en mag dus additiewe effekte hê wanneer dit met ander sentrale senuweesistee-monderdrukkers gekombineer word. Dit mag u kind se risiko om newe-effekte te ontwikkel, verhoog. Moenie CHILL-OUT GUMMIES in kombinasie met hierdie geneesmiddels gee nie, tensy dit onder die toesig van u kind se behandelende dokter is.
U moet ook met ander kruie wat sederende of kalmerende eienskappe het, versigtig wees. Dit sluit ashwagandha, waterhisop, drilgras (perdesterte), kava, neutmuskaat, salie en andere in.

Indien u kind tans enige van die volgende geneesmiddels gebruik, moenie CHILL-OUT GUMMIES vir hom/haar gee voordat u nie die gesamentlike gebruik daarvan met sy/haar dokter, apteker of ander gesondheidsorgverskaffer bespreek het nie:
- Sulfonielureums vir die behandeling van tipe 2-diabetes/suikersiekte. Die kombinasie van CHILL-OUT GUMMIES en sulfonielureums moet liefs in kinders vermy word vanweë die risiko vir lae bloedsuikervlakke.
- Antibiotika vir 'n bakteriële infeksie. Dit is mees raadsaam om CHILL-OUT GUMMIES vir die duur van behandeling met sekere antibiotika te staak. Andersins moet u hierdie antibiotika ten minste 2 ure voor, of 4 tot 6 ure na, CHILL-OUT GUMMIES gee. Bespreek dit asseblief met u dokter of apteker.
- Bloedverdunners soos warfarien. Dit sal nodig wees om gereeld u kind se INR (Internasionale Genormaliseerde Verhouding) te monitor.
- Digoksien vir hartprobleme. CHILL-OUT GUMMIES moet slegs met digoksien onder die toesig van u kind se behandelende dokter gekombineer word.
- Gabapentien vir epilepsie. U moet gabapentien ten minste 2 ure voor, of 4 tot 6 ure na, CHILL-OUT GUMMIES vir u kind gee.
- Skildklierhormone. U kind sal vir die voortgesette effektiwiteit van sy/haar medikasie gemonitor moet word en dit mag nodig wees om bloedtoetse van tyd-tot-tyd te doen (sien **Waarskuwings en voorsorgmaatreëls**).

Soos gesien uit werk wat in laboratoriums gedoen is, is daar 'n moontlikheid dat sommige van die bestanddele in CHILL-OUT GUMMIES die afbraak van medisyne deur die lewer mag beïnvloed. Sodanige middelinteraksies is nie in mense waargeneem nie. Indien u kind egter 'n toename in newe-effekte ervaar of indien u die persepsie het dat sy/haar medisyne minder effektief is nadat dit in kombinasie met CHILL-OUT GUMMIES geneem is, lig asseblief u dokter of apteker daaroor in.

CHILL-OUT GUMMIES met voedsel
CHILL-OUT GUMMIES kan geneem word sonder om maaltye in ag te neem (see **Hoe om CHILL-OUT GUMMIES vir u kind te gee**).

Swangerskap en borsvoeding
CHILL-OUT GUMMIES is vir gebruik in kinders tussen die ouderdomme van 2 en 12 jaar aangedui. Veiligheid en effektiwiteit gedurende swangerskap en borsvoeding is nie vasgestel nie. Gebruik word nie aanbeveel nie.
Indien u swanger is of borsvoed, vermoed dat u swanger is, of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgver-skaffer vir advies voordat u CHILL-OUT GUMMIES neem.

Take wat wakkerheid en konsentrasie vereis
Geen spesifieke studies is gedoen nie. Sommige van die bestanddele in CHILL-OUT GUMMIES het kalmerende eienskappe en mag u kind se vermoë om konsentrasie te verrig wat wakkerheid en konsentrasie verg, nadelig beïnvloed.
Dit is nie altyd moontlik om te voorspel tot watter mate CHILL-OUT GUMMIES met 'n persoon se daaglikse aktiwiteite mag inmeng nie. Maak asseblief seker dat u kind nie die bogenoemde aktiwiteite beoefen voordat u nie bewus is van die mate waartoe CHILL-OUT GUMMIES hom/haar beïnvloed nie.

3. Hoe om CHILL-OUT GUMMIES vir u kind te gee
Moenie u kind se medisyne met enige ander persoon deel nie.
Kinders 2 tot 12 jaar
Gee CHILL-OUT GUMMIES altyd presies soos wat dit in hierdie blaadjie beskryf word of soos wat u dokter, apteker of gesondheidsorgverskaffer gesê het. Raadpleeg u dokter, apteker of gesondheidsorgverskaffer indien u onseker is.

Kou 1 gommetjie voor slaaptyd. Gedurende periodes van erge slaaploosheid of angstigheid, mag kinders tussen 10 en 12 jaar 2 gommetjies voor slaaptyd kou. Die gommetjies kan geneem word sonder om maaltye in ag te neem.
CHILL-OUT GUMMIES behoort soos nodig oor die korttermyn geneem te word. U moet mediese advies inwin indien u kind se simptome vererger of na 14 dae voortduur.

Kinders jonger as 2 jaar
CHILL-OUT GUMMIES word nie vir kinders jonger as 2 jaar aanbeveel nie.

Indien u kind meer CHILL-OUT GUMMIES geneem het as wat hy/sy moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om CHILL-OUT GUMMIES vir u kind te gee
Indien u vergeet om CHILL-OUT GUMMIES vir u kind te gee, gee die dosis so gou as wat u onthou solank dit steeds voor slaaptyd is. Dosisse laat in die nag of vroegoggend mag tot slaperigheid gedurende die dag aanleiding gee.

Indien u kind ophou om CHILL-OUT GUMMIES te gebruik
Indien u kind CHILL-OUT GUMMIES vir 'n verlengde tydperk gebruik het, verval as die dosis die aanbevole dosis oorskry het (sien **Hoe om CHILL-OUT GUMMIES vir u kind te gee**), mag hy/sy onttrekkingsimptome, insluitende slaaploosheid of opwinding, ervaar wanneer gebruik skielik gestaak word. Gesels asseblief met u dokter of apteker oor hoe om die dosis in so 'n geval stelselmatig te verminder.

4. Moontlike newe-effekte
CHILL-OUT GUMMIES kan newe-effekte hê.
Nie alle newe-effekte wat vir CHILL-OUT GUMMIES gemeld is, is in hierdie blaadjie ingesluit nie. Sou u kind se algemene gesondheid agteruitgaan of indien u kind enige ongunstige effekte ervaar terwyl hy/sy CHILL-OUT GUMMIES neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Staak die gebruik van CHILL-OUT GUMMIES en neem u kind onmiddellik na die dokter of die noodafdeling van die naaste hospitaal indien hy/sy enige van die volgende ernstige newe-effekte ervaar:
- Dié waarvoor die frekwensie nie bekend is nie:
  - Galbulte, swelling of die lippe, tong, keel of gesig, moeisame asemhaling, benoude asemhaling of fluitende asemhaling
  - Enige veluitslag.

Indien u kind enige van die bogenoemde ervaar, mag hy/sy 'n ernstige reaksie op CHILL-OUT GUMMIES gehad het en mag hy/sy dringende mediese aandag benodig.

Staak die gebruik van CHILL-OUT GUMMIES en neem u kind so gou as moontlik na die dokter of die noodafdeling van die naaste hospitaal indien hy/sy enige van die volgende newe-effekte ervaar:
- Dié waarvoor die frekwensie nie bekend is nie:
  - Enige visuele probleme (raar)
  - Paradoksale rusteloosheid, opgewondenheid, ongemak, agitasie of intense drome.

Hierdie is almal ernstige newe-effekte. U kind mag mediese aandag benodig.

Meld asseblief die volgende newe-effekte by u dokter aan indien dit voortduur of lastig word:
- Dié waarvoor die frekwensie nie bekend is nie:
  - Dermkanaalirritasie, naarheid, braking, loopmaag
  - Maagpyn of dermkanaalprobleme
  - Duiseligheid, hoofpyn, moegheid, slaperigheid, gebrekkige verstandelike helderheid
  - Toename in eetlus.

Indien u enige newe-effekte opmerk wat nie in hierdie blaadjie genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u kind newe-effekte kry, gesels met u dokter, apteker of verpleegster. U kan newe-effekte ook aan die SAHPRA via die "**6.04 Adverse Drug Reaction Reporting Form**" rapporteer; dit kan aanlyn onder die SAHPRA se publikasies by https://www.sahpra.org.za/Publications/Index/8 gevind word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van CHILL-OUT GUMMIES te voorsien.
Bykomend kan newe-effekte ook aan Vie & Sante (Edms.) Bpk. via e-pos by hello@vieandsante.co.za gerapporteer word.

5. Hoe om CHILL-OUT GUMMIES te berg
Berg teen of benede 25 °C in 'n koel, droë plek. Hou die houer dig toe.
Moenie na die vervaldatum wat op houer aangedui is, gebruik nie.
Moenie ongebruikte CHILL-OUT GUMMIES in dreine en rioolsisteme (bv. toilette) weggooi nie. Besorg alle ongebruikte medisyne aan u apteker terug.
BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.

6. Inhoud van die verpakking en ander inligting
Wat CHILL-OUT GUMMIES bevat
Elke gommetjie bevat:

Trimagnesiumsitraat	104 mg
Wat verskaf elementêre magnesium	12 mg
Matricaria chamomilla L. (Duitse kamille) [blom; 10:1 ekstrak wat 400 mg gedroogdekrui-ekwivalent verskaf]	40 mg
Valeriana edulis var. ciliata (F.G. May) Cronquist *(valeriaan)* [wortel; 5:1 ekstrak wat 160 mg gedroogdekrui-ekwivalent verskaf]	32 mg
Melissa officinalis L. (suurlemoenbalsem) [blaar; 5:1 ekstrak wat 100 mg gedroogdekrui-ekwivalent verskaf]	20mg

Bevat suiker (sukrose) 1 g per gommetjie en glukosestroop 1 g per gommetjie. Die ander bestanddele is sitroensuur, sitruspektien, bedekkingsmateriaal (karnaoebawas, mediumkettingtrigliseriede), kleurstowwe (wortel- en hibiskusekstrak), natuurlike rooibessiegeurstel, natriumsitraat en water.

Hoe CHILL-OUT GUMMIES lyk en inhoud van die verpakking
'n PET-houer met 'n sekuriteitsprop, induksie seël en krimpbedekking wat pers, hartvormige gommetjies met 'n rooibessiegeur, 'n sponsie en 'n gevoude pasiëntinligtingsblaadjie bevat.
Verpakkingsgrootte: 30 gommetjies

Houer van die Sertifikaat van Registrasie
Releaf Pharmaceuticals (Edms.) Bpk.
De Vreugdesingel 14
Dal Josafat
Paarl
7646
Suid-Afrika

Bemark deur: Vie & Sante
www.vieandsante.co.za

Hierdie blaadjie was laas hersien in
Eerste saamgestel in April 2023. 1603/23A

Registrasie/Aansoeknommer
Om deur die Owerheid met registrasie uitgereik te word.

Toegang tot die ooreenstemmende Professionele Inligting
Besoek asseblief https://www.vieandsante.co.za.

PATIENT INFORMATION LEAFLET
CHILL-OUT GUMMIES®

SCHEDULING STATUS: S0

CHILL-OUT GUMMIES®, 3 g, Gummies
Magnesium, German chamomile, valerian, lemon balm
Contains sugar: sucrose 1 g per gummy and glucose syrup 1 g per gummy
Complementary Medicine: Discipline-Specific Combination Product

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority (SAHPRA) for its quality, safety or intended use.

Read this entire leaflet carefully because it contains important information for you.
CHILL-OUT GUMMIES is available without a doctor's prescription to treat a mild childhood illness. Nevertheless, your child still needs to use CHILL-OUT GUMMIES carefully to get the best results from it.
- Keep this leaflet; you may need to read it again.
- Do not share your child's CHILL-OUT GUMMIES with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- Your child must see a doctor if his/her symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What CHILL-OUT GUMMIES are and what it is used for
2. What you need to know before you give CHILL-OUT GUMMIES to your child
3. How to give CHILL-OUT GUMMIES to your child
4. Possible side effects
5. How to store CHILL-OUT GUMMIES
6. Contents of the pack and other information

1. What CHILL-OUT GUMMIES are and what it is used for
CHILL-OUT GUMMIES is a complementary medicine, discipline-specific, combination product that contains magnesium, German chamomile, valerian, and lemon balm. It may support healthy sleep patterns, sleep duration and sleep quality, and may assist to reduce stress, restlessness, and anxiousness in children from 2 to 12 years old.

2. What you need to know before you give CHILL-OUT GUMMIES to your child
Do NOT give CHILL-OUT GUMMIES
- If your child is allergic (hypersensitive) to magnesium citrate, German chamomile (see **Warnings and precautions**), valerian, lemon balm, or any of the other components of the formulation (see **What CHILL-OUT GUMMIES contains**).

Warnings and precautions
CHILL-OUT GUMMIES contains German chamomile, and you should NOT give it to your child if he/she is allergic/hypersensitive to chamomile (see **Do NOT give CHILL-OUT GUMMIES**). It may also cause an allergic reaction in individuals sensitive to the *Asteraceae/Compositæ* family of plants which include ragweed, chrysanthemums, marigolds, daisies, and several other herbs. Immediately stop use if your child demonstrates any sign of hypersensitivity/allergy, such as a skin rash with or without hives, fever, wheezing or a tight chest, or swelling of the face, lips, tongue, or throat (see **Possible side effects**) and consult your doctor.

If your child has been diagnosed with kidney disease, he/she should use CHILL-OUT GUMMIES only under the supervision of his/her treating doctor. It contains magnesium and magnesium excretion is reduced in patients with impaired kidney function.

CHILL-OUT GUMMIES contains lemon balm which may influence thyroid function. If your child has been diagnosed with thyroid problems, he/she should use CHILL-OUT GUMMIES only under the supervision of his/her treating doctor. Your child's doctor will monitor him/her for continued efficacy of his/her medicines, and it may be necessary to do blood tests for thyroid function from time to time (see **Other medicines and CHILL-OUT GUMMIES**).

If your child has been scheduled for a surgical procedure, he/she must stop taking CHILL-OUT GUMMIES at least two weeks before the operation. The ingredients in CHILL-OUT GUMMIES may interact with other medicines commonly used before, during, or after surgical procedures.

Other medicines and CHILL-OUT GUMMIES
Always tell your healthcare provider if your child is taking any other medicine. (This includes all complementary or traditional medicines.)

If your child is receiving treatment with antidepressants, sedatives, or hypnotics (sleeping tablets), it is best to avoid giving them CHILL-OUT GUMMIES, because German chamomile, valerian, and lemon balm also have sedative properties and thus may have additive effects when combined with other central nervous system depressants. This may increase your child's risk of experiencing side effects. Do not give CHILL-OUT GUMMIES in combination with these medicines unless it is under the supervision of your child's treating doctor.
You must also be careful with other herbs that may have sedative or calmative effects, such as ashwagandha, bacopa, horsetail, kava, nutmeg, sage, and others.

If your child is currently using any of the following medicines, do not administer CHILL-OUT GUMMIES before you have discussed their combined use with his/her doctor, pharmacist, or other healthcare provider:
- Sulfonylureas for the treatment of type 2 diabetes. The combination of CHILL-OUT GUMMIES and sulfonylureas are best avoided in children due to the risk of low blood sugar levels.
- Antibiotics for a bacterial infection. It may be best to discontinue CHILL-OUT GUMMIES for the duration of treatment with certain antibiotics. Alternatively, you should administer these antibiotics at least 2 hours before, or 4 to 6 hours after, CHILL-OUT GUMMIES. Please speak to your doctor or pharmacist.
- Blood thinners such as warfarin. Regular monitoring of your child's INR (International Normalised Ratio) will be required.
- Digoxin for heart problems. CHILL-OUT GUMMIES should only be combined with digoxin under the supervision of your child's treating doctor.
- Gabapentin for epilepsy. You must administer gabapentin at least 2 hours before, or 4 to 6 hours after, CHILL-OUT GUMMIES.
- Thyroid hormones. Your child will have to be monitored for continued efficacy of his/her medication and periodic blood tests may be required (see **Warnings and precautions**).

As seen from work done in laboratories, there is a possibility that some of the ingredients in CHILL-OUT GUMMIES may influence breakdown of medicines by the liver. Such medicine interactions have not been seen in humans. However, if your child should experience any increase in side effects or if you have the perception that his/her medicines are less effective after taking them in combination with CHILL-OUT GUMMIES, please inform your doctor or pharmacist.

CHILL-OUT GUMMIES with food
CHILL-OUT GUMMIES can be taken without regard to meals (see How to give **CHILL-OUT GUMMIES to your child)**.

Pregnancy and breastfeeding
CHILL-OUT GUMMIES are indicated for use in children aged 2 to 12 years. Safety and efficacy during pregnancy and lactation have not been established. Use is not recommended.
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 CHILL-OUT GUMMIES.

Tasks requiring alertness and concentration
No specific studies have been conducted. Some of the ingredients in CHILL-OUT GUMMIES have sedative properties and may adversely affect your child's ability to perform tasks requiring alertness and concentration.
It is not always possible to predict to what extent CHILL-OUT GUMMIES may interfere with a person's daily activities. Please ensure that your child do not engage in the above activities until you are aware of the measure to which CHILL-OUT GUMMIES affects him/her.

3. How to give CHILL-OUT GUMMIES to your child
Do not share your child's medicines with any other person.
Children 2 to 12 years
Always give CHILL-OUT GUMMIES exactly as described in this leaflet or as your doctor, pharmacist, or healthcare provider has told you. Check with your doctor, pharmacist, or healthcare provider if you are not sure.

Chew 1 gummy before bedtime. During times of severe sleeplessness or anxiousness, children aged 10 to 12 years may chew 2 gummies before bedtime. Gummies can be taken without regard to meals.
CHILL-OUT GUMMIES should be used on an as-needed basis over the short-term. You should seek medical advice if your child's symptoms worsen or persist after 14 days.

Paediatric population
Children younger than 2 years
CHILL-OUT GUMMIES is not recommended for children under 2 years.

If your child takes more CHILL-OUT GUMMIES than he/she 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 forget to give CHILL-OUT GUMMIES to your child
If you forget to give CHILL-OUT GUMMIES to your child, give the dose as soon as you remember as long as it is still before bedtime. Late night or early morning doses may lead to daytime sleepiness.

If your child stops taking CHILL-OUT GUMMIES
If your child has used CHILL-OUT GUMMIES for an extended period of time, especially in a dosage that exceeded the recommended dosage (see How to give CHILL-OUT GUMMIES to your child), he/she may experience withdrawal symptoms, including sleeplessness or agitation, if use is abruptly discontinued. Please speak to your doctor or pharmacist about tapering the dosage in such an event.

4. Possible side effects
CHILL-OUT GUMMIES can have side effects.
Not all side effects reported for CHILL-OUT GUMMIES are included in this leaflet. Should your child's general health worsen or if he/she experiences any untoward effects while taking CHILL-OUT GUMMIES, please consult your healthcare provider for advice.

Stop use of CHILL-OUT GUMMIES and immediately take your child to the doctor or the emergency department of the nearest hospital if he/she experiences any of the following serious side effects:
- Those for which the frequency is not known:
  - Hives, swelling of the lips, tongue, throat or face, difficult breathing, tightness of the chest, or wheezing
  - Any skin rash.

If your child experiences any of the above, he/she may have had a serious reaction to CHILL-OUT GUMMIES and may require urgent medical attention.

Stop use of CHILL-OUT GUMMIES and take your child to the doctor or the emergency department of the nearest hospital as soon as possible if he/she experiences any of the following side effects:
- Those for which the frequency is not known:
  - Any visual problems (rare)
  - Paradoxical restlessness, excitability, uneasiness, agitation, or vivid dreams.

These are all serious side effects. Your child may need medical attention.

Please report the following side effects to your doctor if they continue or become bothersome:
- Those for which the frequency is not known:
  - Gut irritation, nausea, vomiting, runny stomach
  - Stomach pain or gut problems
  - Dizziness, headache, fatigue, sleepiness, mental dullness
  - Increased appetite.

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

Reporting of side effects
If your child gets side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CHILL-OUT GUMMIES.
In addition, adverse events can also be reported to Vie & Sante (Pty) Ltd via email at hello@vieandsante.co.za.

5. How to store CHILL-OUT GUMMIES
Store at or below 25 °C in a cool, dry place. Keep the container tightly closed.
Do not use after the expiry date stated on the container.
Do not dispose of unused CHILL-OUT GUMMIES in drains or sewerage systems (e.g., toilets). Return all unused medicines to your pharmacist.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information
What CHILL-OUT GUMMIES contain
Each gummy contains:

Trimagnesium citrate	104 mg
Providing elemental magnesium	12 mg
Matricaria chamomilla L. (German chamomile) [flower; 10:1 extract providing 400 mg of dried herb equivalent]	40 mg
Valeriana edulis var. ciliata (F.G. May) Cronquist (valerian) [root; 5:1 extract providing 160 mg of dried herb equivalent]	32 mg
Melissa officinalis L. (lemon balm) [leaf; 5:1 extract providing 100 mg of dried herb equivalent]	20 mg

Contains sugar (sucrose) 1 g per gummy and glucose syrup 1 g per gummy.
Other ingredients are citric acid, citrus pectin, coating material (carnauba wax, medium chain triglycerides), colouring agents (carrot and hibiscus extracts), natural red berries flavour, sodium citrate, and water.

What CHILL-OUT GUMMIES looks like and contents of the pack
A PET container with a security cap, induction seal, and shrink sleeve that contains purple, heart-shaped gummies with red berry flavour, a sponge, and a folded patient information leaflet.
Pack size: 30 gummies

Holder of Certificate of Registration
Releaf Pharmaceuticals (Pty) Ltd
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Marketed by: Vie & Sante
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Registration/Application number
To be allocated by the Authority upon registration.

Access to the corresponding Professional Information
Please visit https://www.vieandsante.co.za.