

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

TAKE IT EASY capsules, vegetarian

Humulus lupulus L. (Hops), *Valeriana officinalis* L. (Valerian), L-theanine, magnesium oxide, calcium carbonate.

Sugar and gelatine free.

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT

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

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

TAKE IT EASY is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use TAKE IT EASY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What TAKE IT EASY is, and what it is used for.
2. What you need to know before you take TAKE IT EASY.
3. How to take TAKE IT EASY.
4. Possible side effects.
5. How to store TAKE IT EASY.
6. Contents of the pack and other information.

1. What TAKE IT EASY is and what it is used for

TAKE IT EASY may assist to aid restful sleep.

2. What you need to know before you take TAKE IT EASY

Do not take TAKE IT EASY:

- if you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of TAKE IT EASY (see **What TAKE IT EASY contains**).

Warnings and precautions

Take special care with TAKE IT EASY:

- If you do not know how TAKE IT EASY affects you, refrain from driving a vehicle, operating machinery, or engaging in any activity that requires your attention.
- If you are taking TAKE IT EASY, it is important to avoid consuming alcohol.
- If you are currently using benzodiazepines, barbiturates, narcotics, anti-depressants, beta-blockers, loperamide, St. John's wort, anti-seizure medication or herbs and supplements with similar effects, inform your doctor or pharmacist before taking TAKE IT EASY.
- If you have liver disease, it is advisable to avoid TAKE IT EASY.

Children

TAKE IT EASY is not indicated for use in children under the age of 18 years.

Other medicines and TAKE IT EASY

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

Tell your doctor or pharmacist if you are currently using:

- Benzodiazepines (used for anxiety and insomnia);
- Barbiturates (used for seizures, anxiety, and insomnia);
- Narcotics (used for pain, anxiety, and respiratory distress);
- Anti-depressants (used for depression);
- Beta-blockers (used for high blood pressure, heart problems, anxiety exc.);
- Loperamide (used for diarrhoea);
- St. John's wort (used for depression);
- Anti-seizure medication (used for seizures);
- Herbs and supplements with similar effects to TAKE IT EASY.

TAKE IT EASY with food and drink

See section 3 (**How to take TAKE IT EASY**).

Pregnancy, breastfeeding and fertility

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 this medicine.

Safety and efficacy of TAKE IT EASY during pregnancy and breastfeeding have not been established. Do not use TAKE IT EASY if you are pregnant or breastfeeding your baby.

Driving and using machines

Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how TAKE IT EASY affects you.

3. How to take TAKE IT EASY

Do not share your medicines with any other person.

Always take TAKE IT EASY exactly as described in this leaflet, or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults from the age of 18 years: Take 1 capsule at night or as recommended by your healthcare practitioner.

If you have the impression that the effect of TAKE IT EASY is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

TAKE IT EASY can be taken with or without food.

If you take more TAKE IT EASY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining TAKE IT EASY with you so the doctor will know what you have taken.

4. Possible side effects

TAKE IT EASY can have side effects.

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

If any of the following happens, stop taking TAKE IT EASY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TAKE IT EASY. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring less frequently:

- headache;
- excitability;
- stomach upset;
- uneasiness;
- dizziness;
- unsteadiness;
- low body temperature (hypothermia);
- reduced concentration;
- morning drowsiness;
- insomnia.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online **under SAHPRA’s publications**: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TAKE IT EASY.

5. How to store TAKE IT EASY

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a cool, dry place, protected from light.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TAKE IT EASY contains

Each capsule contains:

The active substances are:

<i>Humulus lupulus</i> L. (Hops)	38 mg
[dried flowers]	
<i>Valeriana officinalis</i> L. (Valerian)	25 mg
[root, 5:1 extract providing 125 mg of dried herb equivalent]	
Calcium carbonate	278 mg
[providing elemental calcium]	100 mg
L-Theanine	200 mg
Magnesium oxide	86,5 mg
[providing elemental magnesium]	50 mg

The other ingredient is magnesium stearate.
The capsules are made of Hypromellose (HPMC).

Gelatine and sugar free.

What TAKE IT EASY looks like and contents of the pack

A transparent size 0 capsule filled with a white to off-white powder.
TAKE IT EASY capsules are packed in two blisters and packed in an outer carton.

Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street
Sunderland Ridge
Centurion
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info@brunel.co.za

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

The Professional Information for TAKE IT EASY is available on <https://www.brunel.co.za/professional-information/> or can be requested from the contact details above.

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

S0

TAKE IT EASY kapsules, vegetaries

Humulus lupulus L. (Hops), *Valeriana officinalis* L. (Valerian), L-theanien, magnesiumoksied, kalsiumkarbonaat.

Suiker en gelatien vry.

KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.

TAKE IT EASY is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou.

Nietemin, moet jy TAKE IT EASY versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat TAKE IT EASY is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy TAKE IT EASY neem.
3. Hoe om TAKE IT EASY te neem.
4. Moontlike nuwe-effekte.
5. Hoe om TAKE IT EASY te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat TAKE IT EASY is, en waarvoor dit gebruik word

TAKE IT EASY kan rustige slaap aanhelp.

2. Wat jy moet weet voordat jy TAKE IT EASY neem

Moet nie TAKE IT EASY neem:

- indien jy hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van TAKE IT EASY nie (sien **Wat TAKE IT EASY bevat**).

Waarskuwings en voorsorgmaatreëls

Neem spesiale voorsorg met TAKE IT EASY:

- Indien jy nie weet hoe TAKE IT EASY jou affekteer nie, moet nie 'n voertuig bestuur, masjinerie hanteer, of enigiets anders doen wat jou aandag vereis nie.
- Indien jy TAKE IT EASY gebruik is dit belangrik om alkohol te vermy.
- Indien jy tans bensodiasepiene, barbiturate, verdowingsmiddels, antidepressante, beta-blokkers, loperamied, St. John's wort, anti-epileptiese medikasie, of kruie en aanvullings met soortgelyke effekte as TAKE IT EASY gebruik, stel jou dokter in kennis voor jy TAKE IT EASY neem.
- Indien jy 'n lewersiekte het moet jy TAKE IT EASY vermy.

Kinders

TAKE IT EASY word nie aangedui vir kinders onder die ouderdom van 18 jaar nie.

Ander medisyne en TAKE IT EASY

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Stel jou dokter of apteker in kennis as jy tans die volgende gebruik:

- Bensodiasepiene (gebruik vir angs en slapeloosheid);
- Barbiturate (gebruik vir konvulsies, angs en slapeloosheid);
- Verdowingsmiddels (gebruik vir pyn, angs en respiratoriese nood);
- Antidepressante (gebruik vir depressie);
- Beta-blokkers (gebruik vir hoë bloeddruk, hartprobleme, angs ens.);

- Loperamied (gebruik vir diarree);
- St. John's wort (gebruik vir depressie);
- Anti-epileptiese medikasie (gebruik vir konvulsies);
- Kruid en aanvullings met soortgelyke effekte as TAKE IT EASY.

TAKE IT EASY met eet- en drinkgoed

Sien afdeling 3 (**Hoe om TAKE IT EASY te neem**).

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy TAKE IT EASY neem. Die veiligheid en effektiwiteit van TAKE IT EASY tydens swangerskap en borsvoeding is nie vasgestel nie. Moet nie TAKE IT EASY gebruik as jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjiene

Moet nie 'n voertuig bestuur, masjinerie hanteer, of enigiets anders doen wat jou aandag vereis totdat jy weet hoe TAKE IT EASY jou affekteer nie.

3. Hoe om TAKE IT EASY te neem

Moet nie jou medisyne met enige ander persoon deel nie.

Neem TAKE IT EASY altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gewone dosis is:

Volwassenes vanaf 18-jarige ouderdom: Neem 1 kapsule in die aand of soos aanbeveel deur jou gesondheidsorgpraktisyn.

Indien jy die indruk kry dat die uitwerking van TAKE IT EASY te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.

TAKE IT EASY kan met of sonder kos geneem word.

As jy meer TAKE IT EASY neem as wat jy moet

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende TAKE IT EASY saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike nuwe-effekte

TAKE IT EASY kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir TAKE IT EASY gerapporteer is, word in hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy TAKE IT EASY neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om TAKE IT EASY te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige nuwe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op TAKE IT EASY gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Minder algemene nuwe-effekte:

- kopseer;
- opgewondenheid;
- maagprobleme;
- onrustigheid;
- duiseligheid;

- wankeligheid;
- lae liggaamstemperatuur (hipotermie);
- verminderde konsentrasie;
- oggend-lomerigheid;
- slapeloosheid.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van nuwe-effekte

Indien jy nuwe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van TAKE IT EASY te verskaf.

5. Hoe om TAKE IT EASY te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C.
- Stoor in 'n koel, droë plek wat teen lig beskerm is.
- Moet nie in die badkamer stoor nie.
- Moet nie gebruik word na die vervaldatum wat op die karton gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat TAKE IT EASY bevat

Elke kapsule bevat:

Die aktiewe bestanddele is:

<i>Humulus lupulus</i> L. (Hops)	38 mg
[gedroogde blomme]	
<i>Valeriana officinalis</i> L. (Valerian)	25 mg
[wortel, 5:1 ekstrak gelykstaande aan 125 mg gedroogde kruie-ekwivalent]	
Kalsiumkarbonaat	278 mg
[verskaf elementêre kalsium]	100 mg
L-Theanien	200 mg
Magnesiumoksied	86,5 mg
[verskaf elementêre magnesium]	50 mg

Die ander bestanddeel is magnesiumstearaat.

Die kapsules se bestanddeel is Hipromellose (HPMC).

Gelatien en suikervry.

Hoe TAKE IT EASY lyk en die inhoud van die verpakking

'n Deursigtige grootte 0 kapsule gevul met 'n wit tot naaswit poeier.

TAKE IT EASY kapsules word verpak in twee stulpstrokies en in 'n buite-karton.

Houer van die Registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk

Van Tonderstraat 1

Sunderland Ridge

Centurion

0157

info@brunel.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur SAHPRA aangedui word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir TAKE IT EASY is beskikbaar by <https://www.brunel.co.za/professional-information/> of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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