

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

**S0**

### **BRUNEL BASICS VITAMIN D<sub>3</sub> capsules, vegetarian**

Cholecalciferol (vitamin D<sub>3</sub>).

Sugar free.

### **COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT**

#### **D34.11 Vitamins**

**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.**

BRUNEL BASICS VITAMIN D<sub>3</sub> is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BRUNEL BASICS VITAMIN D<sub>3</sub> carefully to get the best results from it.

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

#### **What is in this leaflet**

1. What BRUNEL BASICS VITAMIN D<sub>3</sub> is and what it is used for.
2. What you need to know before you take BRUNEL BASICS VITAMIN D<sub>3</sub>.
3. How to take BRUNEL BASICS VITAMIN D<sub>3</sub>.
4. Possible side effects.
5. How to store BRUNEL BASICS VITAMIN D<sub>3</sub>.
6. Contents of the pack and other information.

#### **1. What BRUNEL BASICS VITAMIN D<sub>3</sub> is and what it is used for**

BRUNEL BASICS VITAMIN D<sub>3</sub> is a source of vitamin D. Vitamin D has many functions, including helping the body to absorb calcium and phosphorous for healthy bones and teeth. Vitamin D is also necessary for muscle function, as well as providing support for the immune system.

#### **2. What you need to know before you take BRUNEL BASICS VITAMIN D<sub>3</sub>**

##### **Warnings and precautions**

None.

##### **Children and adolescents**

BRUNEL BASICS VITAMIN D<sub>3</sub> is safe to give to children from 1 year of age, if they are able to swallow capsules.

##### **Other medicines and BRUNEL BASICS VITAMIN D<sub>3</sub>**

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

##### **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 BRUNEL BASICS VITAMIN D<sub>3</sub>.

There is no evidence that BRUNEL BASICS VITAMIN D<sub>3</sub> will cause harm to you or your baby during pregnancy or breastfeeding.

##### **Driving and using machines**

Safety and efficacy when driving or operating machines have not been established. Do not drive a vehicle, operate machines, or do anything else that requires your attention until you know how BRUNEL BASICS VITAMIN D<sub>3</sub> affects you.

### 3. How to take BRUNEL BASICS VITAMIN D<sub>3</sub>

Do not share your medicines with any other person.

Always take BRUNEL BASICS VITAMIN D<sub>3</sub> 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 and children from 1 year of age:* Take 1 capsule daily.

If you have the impression that the effect of BRUNEL BASICS VITAMIN D<sub>3</sub> is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

BRUNEL BASICS VITAMIN D<sub>3</sub> can be taken with or without food.

### If you take more BRUNEL BASICS VITAMIN D<sub>3</sub> than you should

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

An overdose of vitamin D may cause the following:

- nausea, vomiting and decreased appetite;
- tiredness and weakness;
- change in body temperature (fever or chills);
- dehydration;
- kidney problems;
- stomach pain.

### 4. Possible side effects

BRUNEL BASICS VITAMIN D<sub>3</sub> can have side effects.

Not all side effects reported for BRUNEL BASICS VITAMIN D<sub>3</sub> are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BRUNEL BASICS VITAMIN D<sub>3</sub>, please consult your healthcare provider for advice.

If any of the following happens, stop taking BRUNEL BASICS VITAMIN D<sub>3</sub> 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 BRUNEL BASICS VITAMIN D<sub>3</sub>. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain;
- angina;
- changes in the way your heart beats, for example, if you notice it beating faster;
- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

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**: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BRUNEL BASICS VITAMIN D<sub>3</sub>.

### 5. How to store BRUNEL BASICS VITAMIN D<sub>3</sub>

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.

- Do not store in a bathroom, due to humidity.
- Do not use after the expiry date printed on the label.
- Store in the original packaging.
- 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 BRUNEL BASICS VITAMIN D<sub>3</sub> contains

Each capsule contains:

The active substance is:

Cholecalciferol (Vitamin D<sub>3</sub>) ..... 25 µg (1 000 I.U.)

The other ingredients are magnesium stearate (E572), starch amyral and vegetarian capsule.

### What BRUNEL BASICS VITAMIN D<sub>3</sub> looks like and contents of the pack

90 white, size 1 vegetarian capsules, filled with a white powder and packed in a black PET container.

### Holder of certificate of registration

Brunel Laboratoria (Pty) Ltd

1 Van Tonder Street

Sunderland Ridge

Centurion

0157

[info@brunel.co.za](mailto: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 corresponding Professional Information

The Professional Information for BRUNEL BASICS VITAMIN D<sub>3</sub> 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

### BRUNEL BASICS VITAMIN D<sub>3</sub> kapsules, vegetaries

Cholekalsiferol (vitamien D<sub>3</sub>).

Suikervry.

### KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

#### D34.11 Vitamiene

**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.**

BRUNEL BASICS VITAMIN D<sub>3</sub> is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy BRUNEL BASICS VITAMIN D<sub>3</sub> 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 BRUNEL BASICS VITAMIN D<sub>3</sub> is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy BRUNEL BASICS VITAMIN D<sub>3</sub> neem.
3. Hoe om BRUNEL BASICS VITAMIN D<sub>3</sub> te neem.
4. Moontlike nuwe-effekte.
5. Hoe om BRUNEL BASICS VITAMIN D<sub>3</sub> te bêre.
6. Inhoud van die verpakking en ander inligting.

#### **1. Wat BRUNEL BASICS VITAMIN D<sub>3</sub> is, en waarvoor dit gebruik word**

BRUNEL BASICS VITAMIN D<sub>3</sub> is 'n bron van vitamien D. Vitamien D het baie funksies, insluitend om die liggaam te help om kalsium en fosfor te absorbeer vir gesonde bene en tande. Vitamien D is ook nodig vir spierfunksie, sowel as ondersteuning vir die immuunstelsel.

#### **2. Wat jy moet weet voordat jy BRUNEL BASICS VITAMIN D<sub>3</sub> neem**

##### **Waarskuwings en voorsorgmaatreëls**

Geen.

#### **Kinders en adolessente**

BRUNEL BASICS VITAMIN D<sub>3</sub> is veilig om vir kinders vanaf 1-jarige ouderdom te gee, indien hulle kapsules kan sluk.

#### **Ander medisyne en BRUNEL BASICS VITAMIN D<sub>3</sub>**

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

#### **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 die medisyne neem.

Daar is geen bewyse dat BRUNEL BASICS VITAMIN D<sub>3</sub> skade aan jou of jou baba sal veroorsaak tydens swangerskap of borsvoeding nie.

#### **Bestuur en die gebruik van masjiene**

Dit is nie vasgestel of BRUNEL BASICS VITAMIN D<sub>3</sub> veilig en doeltreffend is tydens bestuur en die gebruik van masjiene nie. Moet nie 'n voertuig bestuur, masjiene hanteer, of enigiets anders doen wat jou aandag vereis totdat jy weet hoe BRUNEL BASICS VITAMIN D<sub>3</sub> jou affekteer nie.

### 3. Hoe om BRUNEL BASICS VITAMIN D<sub>3</sub> te neem

Moet nie jou medisyne met enige ander persoon deel nie.

Neem BRUNEL BASICS VITAMIN D<sub>3</sub> 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 en kinders vanaf 1-jarige ouderdom:* Neem 1 kapsule daagliks.

Indien jy die indruk kry dat die uitwerking van BRUNEL BASICS VITAMIN D<sub>3</sub> te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.

BRUNEL BASICS VITAMIN D<sub>3</sub> kan met of sonder kos geneem word.

### As jy meer BRUNEL BASICS VITAMIN D<sub>3</sub> 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.

'n Oordosis van vitamien D kan die volgende veroorsaak:

- naarheid, braking en verminderde eetlus;
- moegheid en swakheid;
- verandering in liggaamstemperatuur (koors of kouekoors);
- ontwatering;
- nierprobleme;
- maagpyn.

### 4. Moontlike nuwe-effekte

BRUNEL BASICS VITAMIN D<sub>3</sub> kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir BRUNEL BASICS VITAMIN D<sub>3</sub> gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy BRUNEL BASICS VITAMIN D<sub>3</sub> neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om BRUNEL BASICS VITAMIN D<sub>3</sub> te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by 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 BRUNEL BASICS VITAMIN D<sub>3</sub> gehad het. Dringende mediese bystand of hospitalisasie mag nodig wees.

Vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling in jou naaste hospitaal as jy een van die volgende opmerk:

- borspyn;
- angina;
- veranderinge in die manier waarop jou hart klop, byvoorbeeld as jy voel dat dit vinniger klop;
- asemhalingsprobleme.

Hierdie is almal ernstige nuwe-effekte. Jy kan dalk dringende mediese bystand benodig.

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 Reactions 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 BRUNEL BASICS VITAMIN D<sub>3</sub> te verskaf.

## 5. Hoe om BRUNEL BASICS VITAMIN D<sub>3</sub> te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C in 'n koel, droë plek, en beskerm teen lig.
- Moet nie in die badkamer bêre nie, as gevolg van humiditeit.
- Moet nie gebruik word na die vervaldatum soos aangedui op die etiket nie.
- Bêre in die oorspronklike verpakking.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

## 6. Inhoud van die pak en ander inligting

### Wat BRUNEL BASICS VITAMIN D<sub>3</sub> bevat

Elke kapsule bevat:

Die aktiewe bestanddeel is:

Cholekalsiferol (Vitamien D<sub>3</sub>) ..... 25 µg (1 000 I.E.)

Die ander bestanddele is magnesiumstearaat (E572), stysel amiraal en vegetariese kapsule.

### Hoe BRUNEL BASICS VITAMIN D<sub>3</sub> lyk en inhoud van die verpakking

90 wit, grootte 1 vegetariese kapsules, gevul met 'n wit poeier en verpak in 'n swart PET-houer.

### Houer van die registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk

Van Tonderstraat 1

Sunderland Ridge

Centurion

0157

[info@brunel.co.za](mailto:info@brunel.co.za)

### Hierdie inligtingsblad is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

### Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.

### Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir BRUNEL BASICS VITAMIN D<sub>3</sub> 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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