

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

**S0**

#### **BRUNEL BASICS OMEGA-3 softgel capsules**

Omega-3 fish oil (providing Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA)), vitamin E (alphatocopherol).  
Sugar free.

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

##### **D34.12 Multiple Substance Formulation**

**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 OMEGA-3 is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BRUNEL BASICS OMEGA-3 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 OMEGA-3 is and what it is used for.
2. What you need to know before you take BRUNEL BASICS OMEGA-3.
3. How to take BRUNEL BASICS OMEGA-3.
4. Possible side effects.
5. How to store BRUNEL BASICS OMEGA-3.
6. Contents of the pack and other information.

#### **1. What BRUNEL BASICS OMEGA-3 is and what it is used for**

BRUNEL BASICS OMEGA-3 is a supplement to improve your overall health. Fatty acids and vitamin E assists in supporting the health of your heart and blood vessels.

#### **2. What you need to know before you take BRUNEL BASICS OMEGA-3**

##### **Do not take BRUNEL BASICS OMEGA-3:**

- if you are hypersensitive (allergic) to fish or any of the other ingredients of BRUNEL BASICS OMEGA-3 (see **What BRUNEL BASICS OMEGA-3 contains**).

#### **Warnings and precautions**

None.

#### **Children and adolescents**

BRUNEL BASICS OMEGA-3 is safe for children who are able to swallow the capsules.

#### **Other medicines and BRUNEL BASICS OMEGA-3**

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 OMEGA-3.

There is no evidence that BRUNEL BASICS OMEGA-3 will cause harm to you or your baby during pregnancy or breastfeeding.

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

Safety and efficacy when driving or operating machinery have not been established. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how BRUNEL BASICS OMEGA-3 affects you.

### **3. How to take BRUNEL BASICS OMEGA-3**

Do not share medicines with any other person.

Always take BRUNEL BASICS OMEGA-3 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:

Take 2 to 3 capsules daily.

If you have the impression that the effect of BRUNEL BASICS OMEGA-3 is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

BRUNEL BASICS OMEGA-3 can be taken with or without food.

### **If you take more BRUNEL BASICS OMEGA-3 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 BRUNEL BASICS OMEGA-3 with you so the doctor will know what you have taken.

### **4. Possible side effects**

BRUNEL BASICS OMEGA-3 can have side effects.

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

If any of the following happens, stop taking BRUNEL BASICS OMEGA-3 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 OMEGA-3. 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 OMEGA-3.

### **5. How to store BRUNEL BASICS OMEGA-3**

- 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.
- 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 OMEGA-3 contains

Each softgel capsule contains:

The active substances are:

Omega-3 Fish Oil Blend .....	1 000 mg
providing Eicosapentaenoic acid (EPA) .....	180 mg
providing Docosahexaenoic acid (DHA) .....	120 mg
Vitamin E (alphatocopherol) .....	10 mg

The other ingredient is gelatine capsule (bovine).

### What BRUNEL BASICS OMEGA-3 looks like and contents of the pack

90 softgel capsules containing a yellowish oil, packed in a black plastic 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 OMEGA-3 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 OMEGA-3 sagtejel kapsules**

Omega-3 visolie (lewer eikosapentanoësuur (EPA) en dokoheksanoësuur (DHA)),  
vitamien E (alfa-tokoferol).  
Suikervry.

#### **KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING**

##### **D34.12 Formule met verskeie bestanddele**

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

#### **1. Wat BRUNEL BASICS OMEGA-3 is, en waarvoor dit gebruik word**

BRUNEL BASICS OMEGA-3 is 'n aanvulling om jou algemene gesondheid te verbeter. Vetsure en vitamien E help om die gesondheid van jou hart en bloedvate te ondersteun.

#### **2. Wat jy moet weet voordat jy BRUNEL BASICS OMEGA-3 neem**

##### **Moet nie BRUNEL BASICS OMEGA-3 neem:**

- indien jy hipersensitief (allergies) is vir vis of vir enige van die ander bestanddele van BRUNEL BASICS OMEGA-3 nie (sien **Wat BRUNEL BASICS OMEGA-3 bevat**).

#### **Waarskuwings en voorsorgmaatreëls**

Geen.

#### **Kinders en adolessente**

BRUNEL BASICS OMEGA-3 is veilig vir kinders wat die kapsules kan sluk.

#### **Ander medisyne en BRUNEL BASICS OMEGA-3**

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 OMEGA-3 skade aan jou of jou baba sal rig tydens swangerskap of borsvoeding nie.

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

Dit is nie vasgestel of BRUNEL BASICS OMEGA-3 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 OMEGA-3 jou affekteer nie.

### **3. Hoe om BRUNEL BASICS OMEGA-3 te neem**

Moet nie jou medisyne met enige ander persoon deel nie.

Neem BRUNEL BASICS OMEGA-3 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:

Neem 2 tot 3 kapsules daaglik.

Indien jy die indruk kry dat die uitwerking van BRUNEL BASICS OMEGA-3 te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.

BRUNEL BASICS OMEGA-3 kan met of sonder kos geneem word.

### **As jy meer BRUNEL BASICS OMEGA-3 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 BRUNEL BASICS OMEGA-3 saam met jou sodat die dokter kan sien wat jy geneem het.

### **4. Moontlike nuwe-effekte**

BRUNEL BASICS OMEGA-3 kan nuwe-effekte hê.

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

Indien enige van die volgende gebeur, hou op om BRUNEL BASICS OMEGA-3 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 OMEGA-3 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 OMEGA-3 te verskaf.

## 5. Hoe om BRUNEL BASICS OMEGA-3 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.
- 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 OMEGA-3 bevat

Elke sagtejel kapsule bevat:

Die aktiewe bestanddele is:

Omega-3 visolie mengsel.....	1 000 mg
lewer Eikosapentanoësuur (EPA) .....	180 mg
lewer Dokoheksanoësuur (DHA) .....	120 mg
Vitamiën E (alfa-tokoferol) .....	10 mg

Die ander bestanddeel is gelatien kapsule (bees).

### Hoe BRUNEL BASICS OMEGA-3 lyk en inhoud van die verpakking

90 sagtejel kapsules wat 'n gelerige olie bevat, verpak in 'n swart plastiek 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 OMEGA-3 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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