

SEALICIOUS

Read all of this leaflet carefully before you start using SEALICIOUS, because it contains important information for you.

This supplement is available without a doctor's prescription. Nevertheless you still need to use SEALICIOUS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- You must see a doctor if you experience any unfamiliar symptoms, or if symptoms worsen or do not improve.
- Do not share SEALICIOUS with any other person.
- This supplement has not been evaluated by the Medicines Control Council. This supplement is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME (AND DOSAGE FORM):

SEALICIOUS (Enteric coated soft gelatine capsules)

WHAT SEALICIOUS CONTAINS:

Each SEALICIOUS capsule contains:

Each enteric coated capsule contains:	Quantity	%NRV
Fish oil, rich in omega-3 fatty acids BP containing:	500 mg	
Eicosapentaenoic acid (EPA)	165 mg	*
Docosahexaenoic acid (DHA)	110 mg	*
Excipient	q.s.	

*NRV (Nutrient Reference Value) not established.

Other inactive ingredients include gelatin, glycerol, Opadry clear 3K19229, NS Enteric 29Z19241, purified water, Surelease E-7-19040 and Titanium dioxide.

SEALICIOUS contains an enteric coating which protects the fatty acids from gastric acids and increases the intestinal delivery. The enteric coating also helps to mask the "fishy" aftertaste and reduces reflux common to these supplements.

SEALICIOUS is free from artificial flavourants, dairy, preservatives, salt, soy, sugar, wheat and yeast.

WHAT SEALICIOUS IS USED FOR:

SEALICIOUS is an omega-3 fatty acid supplement for adults that has been shown to support overall health and wellbeing, including the appearance and condition of skin, healthy heart and the functioning of the eyes, including vision.

Omega-3 fatty acids are a group of polyunsaturated fatty acids. These are essential fatty acids that are obtained from our diets. Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) are the main dietary omega-3 fatty acids which originate from marine fish oil.

BEFORE YOU TAKE SEALICIOUS:

Do NOT take SEALICIOUS:

- If you are allergic (hypersensitive) to any of the active or inactive ingredients in the formulation.

- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding").

Take special care with SEALICIOUS:

- If you are taking other supplements, since these supplements may contain the same ingredients as SEALICIOUS.
- Are scheduled to have blood tests done. Remember to inform your healthcare professional that you are taking SEALICIOUS.

SEALICIOUS should not be used to replace any medicines prescribed by your doctor.

Consult your doctor if you are taking prescription medicines (see "Taking SEALICIOUS with other medicines").

DO NOT TAKE any other nutritional or herbal supplements without first discussing their combined use with SEALICIOUS with your doctor or pharmacist (see "Taking SEALICIOUS with other medicines").

Nutritional supplements should not replace a balanced diet.

Please discuss the use of SEALICIOUS with your doctor if you have been diagnosed with any of the following conditions:

- Aspirin-sensitivity or if you are an aspirin-sensitive asthmatic, because fish oil containing DHA can lower pulmonary function tests in some aspirin-sensitive patients. If you are an asthmatic with aspirin-sensitivity, caution must be taken when using SEALICIOUS.
- High blood pressure, because blood pressure may be lowered due to additive effects when using a combination of blood pressure medication with DHA and EPA in a fish oil.
- Haemorrhagic disorder (bleeding disorder) or if you are using anti-coagulants (such as warfarin, aspirin, clopidogrel), because SEALICIOUS may affect blood clotting factors and increase the risk of bleeding.

Please discuss the use of SEALICIOUS with your doctor, if any of the above precautions are applicable to you.

Use in children:

SEALICIOUS should not be taken by or given to children under the age of 12 years, as safety has not been established.

Taking SEALICIOUS with food and drink:
SEALICIOUS can be taken with, or without a meal.

Pregnancy and breastfeeding:
SEALICIOUS may only be used if you are pregnant or breastfeeding your baby after your doctor has evaluated all the risks involved, and still feels that it would be beneficial to your health.

If you are pregnant or breastfeeding your baby while taking SEALICIOUS, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving or using machinery:
It is unlikely that SEALICIOUS will affect your ability to drive or operate machinery.

Taking SEALICIOUS with other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of SEALICIOUS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Please discuss the use of the following medicines or substances in combination with SEALICIOUS with your doctor or pharmacist:

- Anti-coagulant or anti-platelet herbs, medicines and supplements, as the combined use may increase the risk of bleeding. Herbs include angelica, clove, garlic, ginger, ginkgo, Panax ginseng, red clover, turmeric and others. Medicines to be used with caution are warfarin, aspirin and clopidogrel.
- Anti-hypertensive herbs and medicines, because fish oils containing DHA and EPA may lower blood pressure when used with herbs such as, andrographis, casein peptides, cat's claw, coenzyme Q-10, fish oil, L-arginine, lycium, stinging nettle, theanine and others. All anti-hypertensive medicines should be used with caution when combined with SEALICIOUS, as they have an additive effect in lowering blood pressure.

HOW TO TAKE SEALICIOUS:

Take one capsule daily with, or without a meal, or as prescribed by a healthcare professional.

DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

If you have the impression that the effect of SEALICIOUS is too strong or too weak, please speak to your doctor or pharmacist.

If you take more SEALICIOUS than you should:

If you take more SEALICIOUS than you should, you may experience an increase in the side-effects listed below (see "POSSIBLE SIDE-EFFECTS").

In the event of an overdose, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.

If you forget to take SEALICIOUS:

Always take SEALICIOUS as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due,

skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

SEALICIOUS may have side-effects.

Not all side-effects reported for SEALICIOUS are included in this leaflet. Should your general health worsen while taking SEALICIOUS, please consult your doctor, pharmacist or other healthcare professional for advice.

Consult your doctor, pharmacist or healthcare professional if you experience any of the following signs and symptoms:

- Gastrointestinal disturbances such as bloating, burping, constipation, diarrhoea, flatulence and nausea are common when high doses are taken.
- Blood clotting side-effects such as bruising, nose bleeds and prolonged bleeding. High dosages of fish oil may decrease blood coagulation (clotting) and increase the risk of bleeding.
- Skin reactions such as acne and eczema.
- Joint, back and muscle pain have been reported with EPA.

Please inform your doctor or pharmacist if you notice any side-effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF SEALICIOUS:

Store at or below 30 °C.

Protect from heat, light and moisture.

Do not take the capsules after the expiry date stated on the package.

Return all unused capsules to your pharmacist.

Store in original container until required for use.

Do not dispose of unused capsules in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

PRESENTATION OF SEALICIOUS:

A white circular, high density polyethylene (HDPE) container with a tamper-evident, white coloured screw cap containing 60 capsules, packed in an outer carton.

IDENTIFICATION OF SEALICIOUS:

Opaque white coloured, oval shaped enteric coated, soft gelatine capsules containing an oily liquid.

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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