

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

CRECHE GUARD BRAIN FUEL

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chew contains

Ingredients	Per 1 chew	Per 3 chews
Total Omega-3 fatty acids providing: Total Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA)	180 mg Not less than 160 mg	540 mg Not less than 480 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Soft brown coloured chews

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

CRECHE GUARD BRAIN FUEL is a health supplement for children that provides the body with omega 3 for the maintenance of good health.

4.2 Posology and method of administration

Children 3 years and older: Chew three daily, or as directed by your healthcare provider.

4.3 Contraindications

- Not for use in children who are hypersensitive to any of the active or inactive ingredients.
- Not for use in children under the age of 3 years.

4.4 Special warnings and precautions for use

- Use with caution in patients with haemorrhagic disorders or in patients using medication affecting blood coagulation, such as anticoagulants. (see **INTERACTIONS**)
- Contains sugar which may have an effect on the glycaemic control of patients with *Diabetes Mellitus*.

4.4 Interaction with other medicines and other forms of interaction

No interaction studies were performed on CRECHE GUARD BRAIN FUEL. The following interactions are noted in the monographs of the active ingredients:

- Anticoagulants/Antiplatelets: there is an increased risk of bleeding with concurrent use of medicines containing omega-3.

4.5 Undesirable effects

Possible side effects include

- gastrointestinal discomfort (nausea, vomiting, heartburn, abdominal pain, bloating, dyspepsia, diarrhoea, constipation)
- eructation (belching) associated with a fishy taste in the mouth

4.6 Overdose

Symptoms of overdosage include stomach upset, nausea, diarrhoea or constipation

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.6 Fats, oils and fatty acids

5.2 PHARMACOLOGICAL ACTION

Omega-3 contains Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA) which help to support cognitive health and brain function.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, corn syrup, gelatin (pork), glycerine, natural flavours (lemon, lime, tropical fruit), palm oil, refined fish oil (anchovy and sardine), soy lecithin

Preservative: herbalox seasoning 0,01 %

Contains sugar 2,18 g/chew

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Individually wrapped chews in a plastic bag, packed in cartons containing 60 chews.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd
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8 REGISTRATION NUMBER

To be allocated

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

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

September 2020