

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

CRECHE GUARD BABY DIGEST EEZE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml contains 1500 Acid Lactase Units of Tolerase L™

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White to cream coloured granules suspended in oil. Odourless and tasteless.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

CRECHE GUARD BABY DIGEST EEZE contains Tolerase L which is an acid lactase that converts lactose into glucose and galactose, thereby assisting with digestion of lactose in milk, and eliminating discomfort such as bloating and abdominal cramps associated with lactose intolerance.

4.2 Posology and method of administration

Infants and children 0-3 years: 10 drops with every feed, or as directed by a healthcare provider.

For breastfed infants, administer drops into mouth immediately prior to breastfeeding. For bottle fed infants, 10 drops can be added into the bottle feed.

Shake well before use.

4.3 Contraindications

Do not use CRECHE GUARD BABY DIGEST EEZE:

- in patients who are hypersensitive to any of the ingredients, including the excipients.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicines and other forms of interaction

There are no known interactions with other medicines.

4.6 Undesirable effects

There are no known side effects.

4.7 Overdose

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

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement

D34.5 Enzymes

5.2 PHARMACOLOGICAL ACTION

Lactose is a milk sugar, naturally present in dairy products. It is digested by the enzyme lactase into glucose and galactose, which are absorbed in the bloodstream. Babies sometimes lack this enzyme and as a result are unable to digest lactose fully. If undigested, lactose reaches the large intestine where it is degraded by its microflora. The resulting by-products may cause symptoms of lactose intolerance including diarrhoea, abdominal cramps, flatulence and nausea. Tolerase® L helps to digest lactose in the stomach thereby preventing the symptoms associated with lactose intolerance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aerosil and medium chain triglyceride oil.

Alcohol and Tartrazine free

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 and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

CRECHE GUARD BABY DIGEST EEZE is available in bottles containing 25ml.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road, Bedfordview, 2007

Tel: (011) 087 0000

www.inovapharma.co.za

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

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