

Professional Information for GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE: GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 15 g serving (2 scoops) contains:	
<i>Avena sativa</i> L. (Oat bran) providing oat beta-glucan (soluble fibre)	3 g

Excipients with known effects:

Contains sweetener: 8,33 mg sucralose per scoop.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

Dry, cream coloured powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK when consumed as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease (CHD). GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK helps support and maintain a healthy digestive system and if taken with meals, may support healthy glucose metabolism for two hours after a meal.

4.2 Posology and method of administration

Adults: Mix 2 scoops per day in 250 ml low fat or fat free milk. Stir well or shake until GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK is mixed into a shake.

Consume immediately. The product will thicken if left to stand.

Do not exceed the recommended daily dosage.

GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK is very high in fibre, for optimal results ensure sufficient water and fluid consumption. Recommended water intake is 8 glasses per day.

Children and adolescents: GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK is not suitable for children under 18 years of age.

4.3 Contraindications

- Hypersensitivity to beta-glucan (oat bran).
- Gluten intolerance.

4.4 Special warnings and precautions for use

Patients suffering from any medical condition, or who are taking any medicine, are advised to consult a healthcare provider before taking GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK.

Gut discomfort or bloating

Gut discomfort or bloating due to increased fibre intake when starting with GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK may be experienced (see section 4.8). If your fibre intake is low start with ½ a scoop of GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK per day and increase it slowly until the full dose is reached, to help the gut adjust to the fibre.

4.5 Interaction with other medicines and other forms of interaction

No known interactions.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK is not likely to affect your ability to drive a vehicle or operate machinery.

4.8 Undesirable effects

GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK powder is generally well tolerated with no side effects, when taken correctly.

Gastrointestinal disorders:

Frequency unknown: Gut discomfort, bloating.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK is important. It allows continued monitoring of the benefit/risk balance of GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 34.10 Saccharides.

GLUCACHOL-22® INSTANT VANILLA FLAVOURED DRINK is an oat bran powder high in beta-glucan (soluble fibre) that supports and maintains a healthy digestive system.

Mechanism of action:

Beta-glucan provides soluble fibre for the maintenance of good health.

5.2 Pharmacokinetic properties

Beta-glucans are resistant to digestion. Levels of propionic acid, a short-chain fatty acid, are increased in faeces after oral intake of beta-glucans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Beta-carotene

Citric acid

Maltodextrin

Silicon dioxide

Sucralose

Tolerase® L (lactase enzyme)

Vanilla flavour

Xanthan gum.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.

Use within 3 months after opening.

6.5 Nature and contents of container

315 g powder and a measuring scoop in a round white plastic tub, with a red coloured plastic screw on lid, containing a patient information leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd.

San Domenico Unit 6

10 Church Street

Durbanville, Cape Town 7551

Marketed by:

At Life Products South Africa (Pty) Ltd.

6 Rautenbach Ave

Wynberg

Sandton, 2090

Gauteng, South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

October 2022.