

Professional Information for GLUCACHOL-22®

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® powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 13,5 g serving (1½ scoops) contains:	
<i>Avena sativa</i> L. (Oat bran) providing oat beta-glucan (soluble fibre)	3 g

Sugar Free.

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® when consumed as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease (CHD). GLUCACHOL-22® 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 1½ scoops per day in drinks, over meals or into yogurt, gravies and soups.

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

Do not exceed the recommended daily dosage.

GLUCACHOL-22® 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® 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®.

Gut discomfort or bloating

Gut discomfort or bloating due to increased fibre intake when starting with GLUCACHOL-22® may be experienced (see section 4.8). If your fibre intake is low start with ½ a scoop of GLUCACHOL-22® 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® is not likely to affect your ability to drive a vehicle or operate machinery.

4.8 Undesirable effects

GLUCACHOL-22® 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® is important. It allows continued monitoring of the benefit/risk balance of GLUCACHOL-22®. 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® 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

None.

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

300 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.

ZAHR900016
2022-10-V1