

# Professional Information for GLUCACHOL-22® INSTANT STRAWBERRY 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 STRAWBERRY 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 STRAWBERRY 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 STRAWBERRY 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 STRAWBERRY 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 STRAWBERRY 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 STRAWBERRY 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 STRAWBERRY FLAVOURED DRINK.

#### Gut discomfort or bloating

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

#### 4.8 Undesirable effects

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

Beetroot juice colour  
Citric acid  
Maltodextrin  
Silicon dioxide  
Strawberry flavour  
Sucralose  
Tolerase® L (lactase enzyme)  
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.