

#### **Australian Government**

### Department of Health, Disability and Ageing

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 206017 GlucoFactors Forte

ARTG entry for Medicine Listed

Sponsor FIT-BioCeuticals Pty Ltd

Postal Address Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102

Australia

ARTG Start Date 13/02/2013

Product Category Medicine

Status Active

Approval Area Listed Medicines

#### Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

#### **Products**

### 1. GlucoFactors Forte

Product Type Single Medicine Product Effective Date 15/11/2025

# Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps convert (state food) into energy

Helps maintain/support healthy blood sugar/glucose

Aid/assist digestion/breakdown of dietary fat

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

### **Indication Requirements**

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

### Standard Indications

No Standard Indications included on Record

### **Specific Indications**

No Specific Indications included on Record

### Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

# **Additional Product information**

# Pack Size/Poison information

Pack Size Poison Schedule

## Components

1 . Formulation 1

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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients	
alpha lipoic acid	200 mg
Biotin	1 mg
chromic chloride hexahydrate	1.28 mg
Equivalent: chromium	250 microgram
chromium picolinate	400 microgram
Equivalent: chromium	50 microgram
Galega officinalis herb flowering Extract dry concentrate	100 mg
Equivalent: Galega officinalis (Fresh)	2 g
Gymnema sylvestre leaf Extract dry concentrate	125 mg
Equivalent: Gymnema sylvestre (Dry)	2 g
Momordica charantia fruit Extract dry concentrate	100 mg
Equivalent: Momordica charantia (Fresh)	3 g
Trigonella foenum-graecum seed Extract dry concentrate	100 mg

### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Equivalent: Trigonella foenum-graecum (Dry)

colloidal anhydrous silica

Gelatin

magnesium stearate

maltodextrin

purified water

400 mg

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