



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	206017	GlucoFactors Forte
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 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	27/04/2022
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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
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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
Equivalent: Trigonella foenum-graecum (Dry)	400 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
Gelatin
magnesium stearate
maltodextrin
purified water

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