Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 290200 Femex Forte

ARTG entry for Medicine Listed

Sponsor Biomedica Nutraceuticals Pty Ltd

Postal Address PO Box 7052, ALEXANDRIA, NSW, 2015

Australia

ARTG Start Date 15/06/2017

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. Femex Forte

 Product Type
 Single Medicine Product
 Effective Date
 26/03/2025

Permitted Indications

Maintain/support general health and wellbeing

Maintain/support healthy digestive system function

Maintain/support healthy digestion

Maintain/support digestive system health

Helps restore good/beneficial/friendly intestinal/gut/bowel flora

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support vaginal healthy flora/microflora

Maintain/support urinary tract health in females Maintain/support urogenital health in females

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to kidney disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

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1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Lactobacillus reuteri 2.5 billion CFU
Lactobacillus rhamnosus 2.5 billion CFU

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

maltodextrin

microcrystalline cellulose

potable water

potassium acetate

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