

For the use of a Registered Medical Practitioner only

1.0 GENERIC NAME AND BRAND NAME

Pre & Probiotics Capsules

COMBINORM™

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatin capsule contains:

Lactobacillus acidophilus	UBLA - 34	2.0 billion cfu
Lactobacillus rhamnosus	UBLR - 58	2.0 billion cfu
Lactobacillus reuteri	UBLRu - 87	2.0 billion cfu
Lactobacillus plantarum	UPLP - 40	1.0 billion cfu
Lactobacillus casei	UBLC - 42	1.0 billion cfu
Lactobacillus fermentum	UBLF - 31	1.0 billion cfu
Bifidobacterium bifidum	UBBB - 55	1.0 billion cfu
Total count:		10 billion cfu

Fructo Oligosaccharide 100 mg

Colours used in Capsule shell: Brilliant Blue FCF, Ponceau 4R, Sunset yellow FCF, Carmoisine, Quinoline Yellow, Titanium Dioxide I.P.

3.0 DOSAGE FORM AND STRENGTH

Refer section 1 & 2

4.0 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATION

COMBINORM

- Helps to treat Bacterial Vaginosis and brings significant relief from associated symptoms like increased discharge, odour and pruritus.
- Restores and maintains normal vaginal flora.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

- **Direction for use:**
- Take one capsule twice daily after food or as directed by the physician.

4.3 CONTRAINDICATIONS

Allergic to any constituents of pre-probiotic.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Warning:

Do not use if hypersensitive to the active ingredient or excipients

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Replaces Version No. 2.0, dated 26th May 2022

4.5 DRUG INTERACTIONS

None known

4.6 USE IN SPECIAL POPULATION

Usage during Pregnancy and Lactation:

Can be used during pregnancy and lactation; it is however preferable to check with your healthcare practitioner.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not known

4.8 UNDESIRABLE EFFECTS

None known.

4.9 OVERDOSE

Excessive doses of COMBINORM do not generally cause undesired effects. Do not exceed the recommended doses.

5.0 PHARMACOLOGICAL PROPERTIES

Bacterial vaginosis results due to deficit in the total number of Lactobacillus and proportional increase in the number of anaerobic bacteria.

BV is a prevalent condition globally, and is associated with adverse outcomes such as infertility, miscarriage, preterm births, and low birth weight infant. Endometrial lining is also affected by the presence of microbes such as Enterococcus, Enterobacteriaceae, Streptococcus, Staphylococcus, and others that affect implantation.

Although antibiotics are effective against BV-associated bacteria and somewhat relieve symptoms, the remission is usually temporary, and many patients relapse after treatment.

Treatment with antibiotics and adjuvant reduces the microbial diversity and causes the recovery of Lactobacillus population. Oral or vaginal probiotics can effectively treat and prevent recurrent BV.

5.1 Mechanism of action

The probiotics, when orally administered, have the natural ability to migrate to the vaginal region from the intestine via perineal and vulval skin.

Probiotics maintain the vaginal pH < 4.5 thereby not allowing a conducive environment for the growth of the pathogenic microbes.

Produces lactic acid, acetic acid and hydrogen peroxide also have antimicrobial activity

Lactobacilli competitively block adhesion of pathogens to the vaginal epithelium thus preventing the spread of infection

Production of bacteriocins that can inhibit the growth of pathogens, including some associated with BV, such as *G. vaginalis*.

In vitro studies have shown that Lactobacillus strains can significantly disrupt Gardnerella vaginalis biofilms and inhibit the growth of pathogens.

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5.2 Pharmacodynamic Properties

Not Applicable

5.3 Pharmacokinetic Properties

Not Applicable

6.0 NON-CLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY/PHARMACOLOGY

None found

7.0 DESCRIPTION

COMBINORM is supplied for oral administration, as a hard gelatin capsule of Pre & Probiotics. Each hard gelatin capsule of COMBINORM contains Lactobacillus acidophilus (UBLA - 34) 2.0 billion cfu ; Lactobacillus rhamnosus (UBLR - 58) 2.0 billion cfu ; Lactobacillus reuteri (UBLRu - 87) 2.0 billion cfu ; Lactobacillus plantarum (UBLP - 40) 1.0 billion cfu ; Lactobacillus casei (UBLc - 42) 1.0 billion cfu ; Lactobacillus fermentum (UBLF - 31) 1.0 billion cfu ; Bifidobacterium bifidum (UBBB - 55) 1.0 billion cfu ; Fructo Oligosaccharide 100 mg.

8.0 PHARMACEUTICAL PROPERTIES

8.1 INCOMPATIBILITIES

Not applicable

8.2 SHELF LIFE

Refer Pack

8.3 PACKAGING INFORMATION

Refer Pack

8.4 STORAGE CONDITION AND HANDLING INSTRUCTIONS

Refer Pack

9.0 PATIENT COUNSELING

Probiotics contain different types of micro-organisms such as yeast (*saccharomyces boulardii*) and bacteria (such as *lactobacillus*, *bifidobacterium*). Micro-organisms (flora) are naturally found in the stomach/intestines/vagina. Some conditions (such as antibiotic use, travel) can change the normal balance of bacteria/yeast. Probiotics are used to improve digestion and restore normal flora. Probiotics have been used to treat bowel problems (such as diarrhea, irritable bowel), eczema, vaginal yeast infections, lactose intolerance, and urinary tract infections. Probiotics are available in foods (such as yogurt, milk, juices, soy beverages) and as dietary supplements (capsules, tablets,

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powders). Different products have different uses. Check the label for information on uses for your particular product. Some diet supplement products have been found to contain possibly harmful impurities/additives. Check with your pharmacist for more details regarding the particular brand you use.

Before using this product, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

If you have any of the following health problems, consult your doctor or pharmacist before using this product: diarrhea lasting more than 2 days (especially if you also have a high fever), weakened immune system (such as due to chemotherapy, HIV infection), recurring vaginal infections, recurring urinary tract infections.

10.0 DETAILS OF MANUFACTURER

Refer Pack for manufacturer details.

Marketed by:

Abbott India Limited

Angel Space, Lifestyle Bldg. No. D-4,
Gala No. 7 to 10 & 17 to 20 Ground Floor,
107 to 110 & 117 to 120 First Floor,
Pimplas Village, Dist. Thane,
Bhiwandi - 421 302, India

11.0 DETAILS OF PERMISSION OR LICENSE NUMBER

Refer Pack for Permission/License details

12.0 DATE OF REVISION

Version 3.0, dated 25/09/2023

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For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com

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