



English

## PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS:

S0

## Progest® Flora-Care Plus Capsules

## Strength

305.26 mg per capsule

## Pharmaceutical form

Solid, DR® (delayed-release) capsule, oral

## Active substances

<i>Lactobacillus acidophilus</i> L.;	
<i>Bifidobacterium longum</i> ,	
<i>bifidum</i> , <i>lactis</i> L. (Probiotic blend)	..... 1 billion CFUs
Ginger root extract	..... 150 mg
Artichoke leaf extract	..... 100 mg
Zinc gluconate	..... 35 mg
Selenium bisglycinate	..... 10 mg
Manganese bisglycinate	..... 10 mg
Folic acid (Vitamin B9)	..... 250 µg
Cholecalciferol (Vitamin D3)	..... 500 IU 12µg

## Sugar-free:

- Does not contain sugar.
- Does not contain sweeteners.

This product is a Complementary Medicine (Category D33.7); and is identified according to its discipline as a Combination Product; which is not registered by the Authority.

**This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.**

### Read all of this leaflet carefully because it contains important information for you

Progest® Flora-Care Plus Capsules is available without a doctor's prescription, for you to treat a mild illness or maintain your health. Nevertheless, you still need to use Progest® Flora-Care Plus Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Progest® Flora-Care Plus Capsules with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

### What is in this leaflet

1. What Progest® Flora-Care Plus Capsules is and what it is used for.
2. What you need to know before you use Progest® Flora-Care Plus Capsules.
3. How to take Progest® Flora-Care Plus Capsules.
4. Possible side effects.
5. How to store Progest® Flora-Care Plus Capsules.
6. Contents of the pack and other information.

#### 1. What Progest® Flora-Care Plus Capsules is and what it is used for.

Progest® FloraCare Plus Capsules are a dietary supplement that contains a blend of beneficial bacteria (probiotics) and herbal extracts, with vitamins and minerals. With DR®, which stands for delayed-release, capsule technology, Progest® Flora-Care Plus is designed to deliver the active substances where they are most effective. As a combination, DR® capsules offer several benefits over other capsule types, such as:

- Probiotic survival through the harsh acidic environment of the stomach.
- Targeted delivery to the small intestine, as some strains are more beneficial in the small intestine.
- Sustained release that helps optimize the colonization of probiotics in the gut and provides a continuous source of nourishment for the growth of healthy gut bacteria.
- Synergistic effect where the prebiotic nutrients protect and sustain the active probiotics, helping them thrive and multiply in the gut.
- Convenience and stability over very costly or wasteful alternatives, as it is easy-to-take, effective support that safeguards the benefits.
- Overcomes the need for users to refrigerate the product, which many other alternatives may require, as they lack the stability of DR® capsules.

This health supplement is indicated to support a healthy digestive system, promote gastrointestinal well-being, maintain the balance of gut flora, and support healthy digestion and mental health. It is also indicated to help support the immune system, and symptomatic relief of minor digestive ailments related to gut dysbiosis by maintaining healthy levels of intestinal flora. Progest® Flora-Care Plus Capsules are indicated for self-administration as a low-risk health supplement, although only a healthcare provider may indicate it as an adjunct treatment to an existing treatment regimen for individual persons. It is not indicated as an alternative therapy to replace conventional medicines or any other treatments prescribed by a healthcare provider. It is not indicated as a cure-all or monotherapy for serious conditions because Progest® Flora-Care Plus Capsules are not intended (nor indicated) to diagnose, treat, prevent, or cure diseases.

#### 2. What you need to know before you use Progest® Flora-Care Plus Capsules.

##### Do not take Progest® Flora-Care Plus Capsules:

- if you are hypersensitive (allergic) to the active substances, or any of the other ingredients Progest® Flora-Care Plus Capsules (listed in section 6).
- if you are on blood thinning medication since coumarins, contained in Progest® Flora-Care Plus Capsules already has a blood-thinning effect (see 'Warnings and precautions').
- if you have a surgery or dental procedure scheduled, for at least two weeks prior.
- without consulting your healthcare provider if you have an existing treatment regimen.

### Warnings and precautions

Special care should be taken with Progest® Flora-Care Plus Capsules:

- if you are already on blood-thinning medication because of the risk of excess blood-thinning effects that could result in bleeding.
- if you have a liver injury because it may not be safe to use medicines not prescribed by your healthcare provider.
- if you have an autoimmune disease or disorder, be watchful and cautious as this medicine may counteract immunosuppressants and strengthen the immune response.
- when pregnant or breastfeeding because safety during pregnancy and lactation has not been established.

### Children

Do not give Progest® Flora-Care Plus Capsules to persons below the age of 18 years. The recommended dosages are specifically calculated to be safe for persons above the age of 18 years only. Keep out of the reach of children.

### Other medicines and Progest® Flora-Care Plus Capsules

Always tell your health care provider if you are taking any other medicine. Other may interfere with or potentiate the effects of Progest® Flora-Care Plus Capsules and vice versa.

### Progest® Flora-Care Plus Capsules with alcohol

We do not recommend that you use Progest® Flora-Care Plus Capsules with alcohol, as this may only further impair the compositional benefits of the active substances.

### Pregnancy and breastfeeding

Safety for use during pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

### Driving and using machines

No undesirable effects on driving and using machines have been reported with Progest® Flora-Care Plus Capsules. It is not always possible to predict to what extent a medicine may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which a medicine affects them.

### Progest® Flora-Care Plus Capsules contains the following excipients:

- Microcrystalline cellulose
- Magnesium stearate

#### 3. How to take Progest® Flora-Care Plus Capsules.

Do not share medicines prescribed for you with any other person. Always take Progest® Flora-Care Plus Capsules exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

- **For adults 18 years and older**, the usual dose is 1–2 capsules, once daily; and this is the maximum recommended daily and/or total doses.
- Each dose should be taken or given with an adequate amount of liquid (preferably a glass of room temperature water).
- Take this product orally only.

#### If you take more Progest® Flora-Care Plus Capsules than you should

- you may experience gastrointestinal discomfort.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

#### If you forget to use Progest® Flora-Care Plus Capsules

- then do not exceed the maximum recommended daily and/or total dose; and
- do not use a double dose to make up for forgotten individual doses.

#### 4. Possible side effects.

Progest® Flora-Care Plus Capsules can have side effects. Not all side effects reported for Progest® Flora-Care Plus Capsules are included in this leaflet. Should you general health worsen or if you experience any untoward effects while taking Progest® Flora-Care Plus Capsules, please consult your health care provider for advice. If any of the following happens, stop taking/using Progest® Flora-Care Plus Capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

These are all very serious side effects and could be signs of an allergic reaction or hypersensitivity to Progest® Flora-Care Plus Capsules. You may need urgent medical attention or hospitalization. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects 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>. By reporting side effects, you can help provide more information on the safety of Progest® Flora-Care Plus Capsules.

#### 5. How to store Progest® Flora-Care Plus Capsules.

Store all medicines out of reach of children. Store in a cool, dry place at temperatures of 59–77 °F, equivalent to 15–25 °C, and with ambient humidity between 35 % and 65 %. Do not refrigerate or freeze. Store in the original package or container. Protect from direct sunlight and moisture. Do not use it after the expiry date stated on the label. Do not use Progest® Flora-Care Plus Capsules if you notice abnormal appearance or unpleasant odor, as the product may be expired or was improperly stored. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems. Please recycle the empty containers.

#### 6. Contents of the pack and other information.

##### What Progest® Flora-Care Plus Capsules contains

The active substances are as listed at the start of this leaflet. The other ingredients are listed as excipients (see section 2) in this leaflet.

##### What Progest® Flora-Care Plus Capsules looks like and contents of the pack

Progest® Flora-Care Plus Capsules come in cartons of 10 and 30 capsules. Progest® Flora-Care Plus Capsules have a solid capsule dosage form with a specific appearance: white capsule with a 23 mm lock length, sealed inside of a blister-pack. The blister-pack also has the product label printed on the foil for identification purposes. The carton acts as the secondary packaging for storage, also showing the proper labeling.

##### Holder of Certificate of Registration

Tara Pharmaceuticals (Pty) Ltd  
36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

##### Application number

DCFS-db4f9a  
Act 101/1965

##### Access to corresponding Professional Information

<https://www.tarapharmaceuticals.com/items>



Afrikaans

## PASIËNTINLIGTINGSPAMFLET

## SKEDULERINGSSTATUS:

S0

## Progest® 'Flora-Care Plus' Kapsules

**Sterkte**  
305.26 mg per kapsule

**Farmaseutiese vorm**  
Solied, 'DR® (delayed-release)' kapsule, oraal

## Active bestanddele

<i>Lactobacillus acidophilus</i> L.;	
<i>Bifidobacterium longum</i> ,	
<i>bifidum</i> , <i>lactis</i> L. (Probiotiese mengsel)	1 billion CFUs
Gemmer wortel ekstrak	150 mg
Artisjokblaar ekstrak	100 mg
Sinkglukonaat	35 mg
Seleebisglisinaat	10 mg
Mangaanbisglisinaat	10 mg
Foliensuur (Vitamiën B9)	250 µg
Cholekalsiferol (Vitamiën D3)	500 IE 12µg

## Suiker-vry:

- Bevat nie suiker nie.
- Bevat nie versoeters nie.

Hierdie produk is 'n Komplementêre Medisyne (Kategorie D33.7); en word volgens sy dissipline geïdentifiseer as 'n Kombinasie Produk; wat nie deur die Owerheid geregistreer is nie.

**Hierdie ongeregisteerde medisyne is nie deur die SAHPRA geëvalueer vir die gehalte, veiligheid of beoogde gebruik daarvan nie.**

### Lees al hierdie pamflet aandagtig deur, want dit bevat belangrike inligting vir jou

Progest® 'Flora-Care Plus' Kapsules is beskikbaar sonder 'n voorskrif van 'n dokter, sodat u 'n ligte siekte kan behandel of u gesondheid kan handhaaf. Nietemin moet u Progest® 'Flora-Care Plus' Kapsules steeds versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Miskien moet u dit weer lees.
- Moenie Progest® 'Flora-Care Plus' Kapsules met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter besoek as u simptome na 7 dae vererger of nie verbeter nie.

### Wat is in hierdie pamflet

1. Wat Progest® 'Flora-Care Plus' Kapsules is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u Progest® 'Flora-Care Plus' Kapsules gebruik.
3. Hoe om Progest® 'Flora-Care Plus' Kapsules te neem.
4. Moontlike nuwe-effekte.
5. Hoe om Progest® 'Flora-Care Plus' Kapsules te stoor.
6. Inhoud van die pak en ander inligting.

#### 1. Wat Progest® 'Flora-Care Plus' Kapsules is en waarvoor dit gebruik word.

Progest® FloraCare Plus Kapsules is 'n dieetaanvulling wat 'n mengsel van voordelige bakterieë (probiotika) en kruië-ekstrakte, met vitamiene en minerale bevat. Met DR®, wat staan vir 'delayed-release' kapsule-tegnologie, is Progest® Flora-Care Plus ontwerp om die aktiewe stowwe te lewer waar dit die doeltreffendste is. As 'n kombinasie bied DR®-kapsules verskeie voordele bo ander kapsuletypes, soos:

- Probiotiese oorlewing deur die rowwe suur omgewing van die maag.
- Geteikende aflewering na die dunderm, aangesien sekere stamme van probiotika meer voordelig in die dunderm is.
- Volgehoue vrystelling wat help om die kolonisasie van probiotika in die ingewande te optimaliseer en 'n deurlopende bron van voeding bied vir die groei van gesonde dermbakterieë.
- Sinergistiese effek waar die probiotiese voedingsstowwe die aktiewe probiotika beskerm en onderhou, wat hulle help floreer en in die ingewande vermeerder.
- Gerief en stabiliteit bo baie duur of verkostende alternatiewe, want dit is maklik om te neem, doeltreffende ondersteuning wat die voordele beskerm.
- Oorkom die behoefte vir gebruikers om die produk te verkoop, wat baie ander alternatiewe mag vereis, aangesien hulle nie die stabiliteit van DR®-kapsules het nie.

Hierdie gesondheidsaanvulling is aangedui om 'n gesonde spysverteringstelsel te ondersteun, gastroïntestinale welstand te bevorder, die balans van dermflora te handhaaf, en gesonde spysvertering en geestesgesondheid te ondersteun. Dit word ook aangedui om te help om die immuunstelsel te ondersteun, en simptomatiese verligting van geringe spysverteringskwale wat verband hou met dermdysbiose deur gesonde vlakke van dermflora te handhaaf. Progest® Flora-Care Plus Kapsules word vir selftoediening as 'n laerisiko-gesondheidsaanvulling aangedui, alhoewel slegs 'n gesondheidsorgverskaffer dit as 'n bykomende behandeling tot 'n bestaande behandelingsregime vir individuele persone mag aandui. Dit is nie aangedui as 'n alternatiewe terapie om konvensionele medisyne of enige ander behandelings wat deur 'n gesondheidsorgverskaffer voorgeskryf word, te vervang nie. Dit is nie aangedui as 'n genesing of monoterapie vir ernstige toestande nie, want Progest® Flora-Care Plus-kapsules is nie bedoel (ook nie aangedui nie) om siektes te diagnoseer, te behandel, te voorkom of te genees nie.

#### 2. Wat u moet weet voordat u Progest® 'Flora-Care Plus' Kapsules gebruik.

##### Moenie Progest® 'Flora-Care Plus' Kapsules neem:

- as u hipersensitief (allergies) is vir die aktiewe bestanddele, of enige van die ander bestanddele Progest® 'Flora-Care Plus' Kapsules (gelys in afdeling 6) nie.
- as u bloedverduunningsmedikasie gebruik nie, aangesien kumariene, vervat in Progest® 'Flora-Care Plus' Kapsules, reeds 'n bloedverduunnings effek het (sien 'Waarskuwings en voorsorgmaatreëls').
- as u 'n operasie of tandheelkundige prosedure geskeduleer het, vir ten minste twee weke tevore nie.
- sonder om u gesondheidsorgverskaffer te raadpleeg as u 'n bestaande behandelingsregime het nie.

### Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met Progest® 'Flora-Care Plus' Kapsules:

- as u reeds bloedverduunningsmedikasie gebruik as gevolg van die risiko van oortollige bloedverduunnings-effekte en moontlike bloeding.
- as u 'n lewerbesering het, en u 'n gesondheidsorgverskaffer moet raadpleeg.
- as u 'n outo-immuun siekte of afwyking het, wees waaksaam en versigtig, aangesien hierdie medisyne immuunonderdrukkers kan teenwerk en die immuunstelsel kan versterk.

### Kinders

Moenie Progest® 'Flora-Care Plus' Kapsules aan persone onder die ouderdom van 18 jaar gee nie. Die aanbevole dosisse word spesifiek bereken om slegs veilig te wees vir persone bo die ouderdom van 18 jaar. Hou buite bereik van kinders.

### Ander medisyne en Progest® 'Flora-Care Plus' Kapsules

Vertel altyd jou gesondheidsorgverskaffer as u enige ander medisyne gebruik. Ander medisyne kan inmeng met of die effekte van Progest® 'Flora-Care Plus' Kapsules versterk, en omgekeerd.

### Progest® 'Flora-Care Plus' Kapsules met alkohol

Ons beveel nie aan dat u Progest® 'Flora-Care Plus' Kapsules met alkohol gebruik nie, aangesien dit die voordele wat uit die aktiewe bestanddele verkry kan word, net verder kan benadeel.

### Swangerskap en borsvoeding

Veiligheid vir gebruik tydens swangerskap en borsvoeding is nie vasgestel nie. As u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik.

### Bestuur en gebruik masjiene

Moenie ongewenste effekte op die bestuur en gebruik van masjiene is aangemeld met Progest® 'Flora-Care Plus' Kapsules nie. Dit is nie altyd moontlik om te voorspel in water mate 'n medisyne die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle bewus is van die matriëel waarop 'n medisyne hulle beïnvloed nie.

### Progest® 'Flora-Care Plus' Kapsules bevat die volgende eksipiënte:

- Mikrokristallynesellulose
- Magnesiumstearaat

### 3. Hoe om Progest® 'Flora-Care Plus' Kapsules te neem.

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd Progest® 'Flora-Care Plus' Kapsules presies soos beskryf in hierdie pamflet of soos u dokter, apteker of verpleegster u vertel het. Raadpleeg u dokter, apteker of verpleegster as u nie seker is nie.

- **Vir volwassenes 18 jaar en ouer** is die gewone dosis 1–2 kapsules, een maal per dag; en dit is die maksimum aanbevole daaglikse en/of totale dosisse.
- Elke dosis moet geneem of gegee word met 'n voldoende hoeveelheid vloeistof (verkslik 'n glas kamertemperatuurwater).
- Neem hierdie produk slegs mondelings.

### As u meer Progest® 'Flora-Care Plus' Kapsules neem as wat u moet

- U kan gastro-intestinale ongemak ervaar.
- In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van die twee beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

### As u vergeet om Progest® 'Flora-Care Plus' Kapsules te gebruik

- Moenie die maksimum aanbevole daaglikse en/of totale dosis oorskry nie; en
- Moenie 'n dubbeldosis gebruik om vergete individuele dosisse op te maak nie.

### 4. Moontlike nuwe-effekte.

Progest® 'Flora-Care Plus' Kapsules kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Progest® 'Flora-Care Plus' Kapsules gerapporteer word, word in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of as u enige onaangename gevolge ervaar terwyl u Progest® 'Flora-Care Plus' Kapsules neem, raadpleeg asseblief u gesondheidsorgverskaffer vir raad.

As een van die volgende gebeur, hou op om Progest® 'Flora-Care Plus' Kapsules te neem / te gebruik en vertel u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal:

- 'swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak',
- 'uitslag of jeuk',
- 'flou'

Dit is alles baie ernstige nuwe-effekte en kan tekens wees van 'n allergiese reaksie of hipersensitiwiteit vir Progest® 'Flora-Care Plus' Kapsules. U mag dringende mediese aandag of hospitalisasie benodig. As u enige nuwe-effekte sien wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

### Verlagdoening van nuwe-effekte

As u nuwe-effekte kry, praat met jou dokter, apteker of verpleegster. U kan ook nuwe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte te rapporteer, kan u help om meer inligting oor die veiligheid van Progest® 'Flora-Care Plus' Kapsules te verskaf.

### 5. Hoe om Progest® 'Flora-Care Plus' Kapsules te stoor.

Stoor alle medisyne buite bereik van kinders. Berg op 'n koel, droë plek by temperatuur van 59-77 °F, gelykstaande aan 15-25 °C, en met omgewingsvogtigheid tussen 35 % en 65 %. Moenie verkoel of vries nie. Berg in die oorspronklike verpakking of hou. Beskerm teen direkte sonlig en vog. Moenie dit gebruik na die vervaldatum wat op die etiket aangedui word nie. Moenie Progest® 'Flora-Care Plus' Kapsules gebruik as u abnormale voorkoms of onaangename reuk opmerk nie, aangesien die produk verval het of onbehoorlik gestoor is. Stuur alle ongebruikte medisyne terug aan u apteker. Moenie ongebruikte medisyne in dreine of rioelstelsels weggooi nie. Herwin asseblief die leë houers.

### 6. Inhoud van die pak en ander inligting.

#### Wat Progest® 'Flora-Care Plus' Kapsules bevat

Die aktiewe bestanddele is soos aan die begin van hierdie pamflet gelys. Die ander bestanddele word in hierdie pamflet as eksipiënte (sien afdeling 2) gelys.

#### Hoe Progest® 'Flora-Care Plus' Kapsules lyk en inhoud van die pak

Progest® Flora-Care Plus-kapsules kom in kartonne van 10 en 30 kapsules. Progest® Flora-Care Plus Kapsules het 'n soliede kapsule-doseervorm met 'n spesifieke voorkoms: wit kapsule met 'n 23 mm slotlengte, versêel binne-in 'n blisterverpakking. Die blisterverpakking het ook die produk-etiket op die foelie gedruk vir identifikasiedoeleindes. Die karton dien as die sekondêre verpakking vir berging, en toon ook die korrekte etikettering.

#### Houer van Registrasiesertifikaat

Tara Pharmaceuticals (Pty) Ltd  
36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

#### Aansoeknommer

DCFS-db4f9a  
Wet 101/1965

#### Toegang tot ooreenstemmende professionele inligting

<https://www.tarapharmaceuticals.com/items>