

Progast

FLORACARE FORTE CAPSULES

Progast FLORACARE Forte (Capsules) 10's & 30's

SCHEDULING STATUS

Not scheduled.

COMPOSITION

ACTIVE INGREDIENTS:

	MG PER CAPSULE:
Probiotic 4 strain	= 5 billion CFUs
Lactobacillus acidophilus	
Bifidobacterium longum	
Bifidobacterium bifidum	
Bifidobacterium lactis	
Manganese AAC 10%	10 mg
(equivalent to 1 mg elemental Manganese)	
Selenium AAC 0,2%	10 mg
(equivalent to 0.02 mg (20 µg) elemental Selenium)	
Zinc Gluconate	35 mg
(equivalent to 4.9 mg elemental Zinc)	
Beta 1,3 glucan	50 mg
Vitamin D3	500 IU
(equivalent to 12.5 µg cholecalciferol)	
Zingiber officinale (Ginger extract)	150 mg
(root, extract standardised to gingerol 5%)	
Perilla frutescens (Perilla leaf extract)	500 mg
(leaf extract, as 100 mg of a 5:1 extract)	
Folic acid (Vitamin B9)	250 µg
C.F.U. = Colony Forming Units at the time of manufacture.	

PHARMACOLOGICAL CLASSIFICATION

A 32.2 Other Pro-Biotics/Digestives.

DRcaps™ capsules: made from a novel hypromellose formulation, are uniquely resistant to a low pH environment such as that found in the stomach. The unique characteristics of DRcaps™ capsules are employed by Progast FLORACARE Forte to provide efficient, targeted delivery.

Sensitive ingredients (e.g. probiotics, enzymes) can be protected through to their delivery in the intestines.

PHARMACOLOGICAL ACTION

Probiotics are live micro-organisms (bacteria and yeast) which when administered in adequate amounts result in a health benefit for the person taking them.

1. Lactobacillus acidophilus

Supports digestive and immune health, is acid and bile resistant and provides long lasting colonization*

2. Bifidobacterium lactis

Promotes a healthy inflammatory response including allergy response and supports the growth of other beneficial bacteria*

3. Bifidobacterium longum

Promotes a healthy stress response and may reduce gastrointestinal symptoms*

4. Bifidobacterium bifidum

Supports healthy blood sugar levels already in the normal range and may help alleviate gastrointestinal symptoms such as diarrhea*

MECHANISM OF ACTION:

1) Probiotics:

There are multiple theories regarding the mechanism of action of probiotics. The following three categories have been identified:

a. Modulation of host immune response

Helps to enhance and strengthen the reaction of the immune system in the gastrointestinal tract against harmful bacteria.

b. Enhanced epithelial barrier function

Helps to ensure a healthy bowel lining, preventing harmful bacteria from invading the epithelium.

c. Anti-microbial effects

Helps prevent bacterial adherence to and infiltration of the bowel lining.

2) Beta 1,3 Glucan:

Beta Glucan modulates or activates but never stimulates the immune system.

3) Zingiber officinale:

A highly potent antioxidant and anti-inflammatory agent that helps to relax the smooth muscles in the gut lining and helps with digestion promoting a healthy gut, relieving gastro-intestinal pain, nausea and facilitates the healing of ulcers.

4) Perilla Leaf extract: Human in-vitro and ex-vivo studies showed:

Helps improve Gastro-intestinal symptoms such as occasional bloating, gas, fullness and abdominal discomfort

- Supports digestive health

- Helps with transit of food through your gut

- Helps support a normal inflammatory response in your gut

- Helps improve daily regularity

The mode of action appears to interact with your neurological system and counteract the effects of stress and other psychosocial factors via your gut-brain axis!

5) Folic acid: is a group of water-soluble B vitamins that help to control gene expression and protect against rogue cells multiplying into cancer. Because the wall of your gut is perpetually renewed as new cells get pushed to the surface and old cells slough off into your digestive tract, you need nutrients to safeguard this replication process. Folate helps to control inflammation.

6) Vitamin D3: Vitamin D is a fat-soluble vitamin. Vitamin D deficiency has been linked to a number of gut disorders, including:

- Colon cancer

- Diverticulitis

- Inflammatory bowel disease

- Irritable bowel syndrome (IBS)

Vitamin D3 also acts as an anti-bacterial in the gut and wards off infection.

7) Zinc Gluconate: Zinc activates digestive enzymes, ensuring your meal is fully broken down and used. Zinc also strengthens the barrier of the gut wall, making it an indispensable trace mineral for those with leaky gut.

8) Selenium AAC: Selenium is an antioxidant mineral. Selenium is found in antioxidant enzymes that minimize the damage of free radical stress and reduce inflammation. Selenium is also needed to make active thyroid hormone.

9) Manganese AAC: Manganese "turns on" the enzymes that break down carbohydrates, amino acids and cholesterol.

INDICATIONS:

Helps in restoring the balance of natural flora in conditions such as diarrhoea, traveller's diarrhoea and antibiotic associated diarrhoea.

- Assists in decreasing the duration and severity of diarrhoea

- Aids in decreasing the incidence and severity of traveller's diarrhoea

- Assists in restoring and maintaining intestinal flora during antibiotic therapy

- Aids in decreasing the incidence and severity of antibiotic related diarrhoea

- Enhances the protective barrier of the digestive tract

- Assists with general intestinal health

Helps in alleviating symptoms associated with Irritable Bowel Syndrome (IBS).

- Aids in relieving symptoms of abdominal discomfort, pain and intestinal spasms associated with digestive problems

- Aids in alleviating bloating and flatulence

- Enhances digestion

- Enhances the protective barrier of the digestive tract

CONTRA-INDICATIONS AND WARNINGS:

This product is meant for use along with medication as prescribed by a physician (if applicable) and other supportive measures such as rehydration.

This product is not meant to be taken in place of any treatment prescribed by a physician.

Diarrhoea is a potentially severe/fatal condition and appearance of bloody stools, fever and dehydration necessitates consultation with a physician.

This product should be taken with caution, by those who are immune-suppressed as it has the potential to cause systemic bacterial disease in such patients. Use only when directed by a physician. Examples of immune-suppressed patients include:

- Patients on active chemotherapy for cancer

- Patients receiving immunosuppressant medication for transplants and conditions such as rheumatoid arthritis

This product has not been evaluated in pregnant and lactating mothers.

Do not take if allergic to any of the ingredients contained in the product.

Diabetics and people taking blood thinning medication (Warfarin) should take Progast FLORACARE Forte under medical supervision as Progast FLORACARE Forte may enhance the effect of these medications.

SAFETY

Probiotics are on the GRAS (Generally Recognized as Safe) list of the FDA. Please contact your physician if you are unsure about any particulars of this product.

INTERACTIONS

There are no known medicinal interactions with the concomitant administration of other medicines.

PREGNANCY AND LACTATION

This product has not been evaluated in pregnant and lactating (breastfeeding) mothers. Woman who are pregnant or breastfeeding should consult their doctor before using this product.

DOSAGE AND DIRECTIONS FOR USE

Adults and children 12 years and older:

Acute Dosage:

Take one capsule twice daily 30 minutes before a meal or as prescribed by a healthcare professional.

Chronic Dosage:

Take one capsule daily 30 minutes before breakfast or as prescribed by a healthcare professional.

SWALLOW WITH A GLASS OF WATER. DO NOT TAKE WITH WARM LIQUIDS. DO NOT OPEN THE CAPSULE.

During antibiotic therapy, the product should be taken at least 3 hours after administration of the antibiotic (i.e. in the interval between one dose of antibiotic and the next).

SIDE-EFFECTS

Please refer to "Contra-Indications, Warnings and Interactions".

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

No clinical manifestations of overdose have been reported.

IDENTIFICATION

PROGAST FLORACARE FORTE: White capsules, containing a white/brown -coloured powder.

PRESENTATION

Packs of 10's and 30's capsules, in a blister pack.

Blister packs of 10's or 30's capsules in a box.

STORAGE INSTRUCTIONS

Store in a cool, dry place, below 25 °C, protected from direct sunlight.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Will be allocated by Council upon registration.

NAME OF APPLICANT

Tara Pharmaceuticals (Pty) Ltd.

MARKETED AND DISTRIBUTED BY TARA PHARMACEUTICALS (Pty) Ltd

Unit 9, Fish Eagle Park, Somerset West, South Africa.

CO. REG. NO. 1996/011192/07

TEL: 0861118272

PROGAST IS MANUFACTURED IN SOUTH AFRICA.

DATE OF PUBLICATION OF THE PACKAGE INSERT

January 2018

This medicine has not been evaluated by SAHPRA.

This medicine is not intended to diagnose, treat, cure or prevent any disease.

NUPIN124/03



PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Not Scheduled

PROPRIETARY NAME & DOSAGE FORM

PROGAST FLORACARE FORTE capsules

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

PROGAST FLORACARE FORTE is available without a doctor's prescription for you to treat a mild illness. Never the less you still need to use PROGAST FLORACARE FORTE carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Do not share PROGAST FLORACARE FORTE with any other person.

Consult your pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve within 30 days.

WHAT PROGAST FLORACARE FORTE CONTAINS

ACTIVE INGREDIENTS:

	MG PER CAPSULE:
Probiotic 4 strain	= 5 billion CFUs
Lactobacillus acidophilus	
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Bifidobacterium bifidum	
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Perilla frutescens (Perilla leaf extract)	500 mg
(leaf extract, as 100 mg of a 5:1 extract)	
Folic acid (Vitamin B9)	250 µg

WHAT PROGAST FLORACARE FORTE IS USED FOR

It helps in restoring the balance of natural flora in conditions such as diarrhoea, traveller's diarrhoea and antibiotic associated diarrhoea.

- Assists in decreasing the duration and severity of diarrhoea

- Aids in decreasing the incidence and severity of traveller's diarrhoea

- Assists in restoring and maintaining intestinal flora during antibiotic therapy

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- Enhances the protective barrier of the digestive tract

- Assists with general intestinal health

Helps in alleviating symptoms associated with Irritable Bowel Syndrome (IBS).

- Aids in relieving symptoms of abdominal discomfort, pain and intestinal spasms associated with digestive problems

- Aids in alleviating bloating and flatulence

- Enhances digestion

- Enhances the protective barrier of the digestive tract

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Progast

FLORACARE FORTE CAPSULES

Progast FLORACARE Forte (Kapsules) 10's & 30's

SKEDULERINGSTATUS

Nie geskeduleer nie.

SAMESTELLING

AKTIEWE BESTANDDELE:

Probiotika 4 soorte	MG PER KAPSULE: = 5 biljoen KVEs
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Bifidobacterium longum	
Bifidobacterium bifidum	
Bifidobacterium lactis	
Mangaan AAC 10%	10 mg (gelykstaande aan 1 mg elementaal Mangaan)
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Sink Glukonaat	35 mg (gelykstaande aan 4,9 mg elementaal Sink)
Beta 1,3 glukaan	50 mg
Vitamien D3	500 IU (gelykstaande aan 12,5 µg cholecalciferol)
Zingiber officinale (Gemmer ekstrak)	150 mg (wortel, ekstrak standaard aan gingerol 5%)
Perilla frutescens (Perilla blaar ekstrak)	500 mg (blaar ekstrak, as 100 mg van 'n 5:1 ekstrak)
Foliensuur (Vitamien B9)	
K.V.E.=Kolonie Vormende ten tye van vervaardiging.	

FARMAKOLOGIESE KLASIFIKASIE

A 33.2. Ander Probiotika/Verteringsmiddels

DRcaps™ kapsules: gemaak van 'n nuwe hipromellose formulasié, is uniek bestand teen 'n lae pH omgewing soos gevind in die maag. Die unieke eienskappe van DRcaps™ kapsules word deur Progast FLORACARE Forte gebruik om doeltreffende, doelgerigte aflewing te verskaaf. **Gevoelige bestanddele (bv. Probiotika, ensieme) kan beskermt word tot hul aflewing in die dunderm.**

FARMAKOLOGIESE WERKING

Probiotika is lewende mikroorganismes (bakterieë en gis) wat, as dit in voldoende hoeveelhede toegedien word, 'n gesondheidsvoordeel inhoud vir die persoon wat dit inneem.

1. Lactobacillus acidophilus

Ondersteun versteening en umum gesondheid, is suur en gal weerstandig en voorsien langermyn kolonisasie. **Supports***

2. Bifidobacterium lactis

Bevorder a gesonde inflammatoriiese en allergies reaksie en ondersteun en die groei van ander goeie bakterieë. **Promotes***

3. Bifidobacterium longum

Bevorder in gesonde stress reaksie en mag gastrointestinale symptom verminder

4. Bifidobacterium bifidum

Ondersteun gesonde bloop suiker vlakte wat reeds in normale vlakte val en mag help on gastrointestinale symptome soos diarrhoea te verlig

WERKINGSMEGANISME

1) Probiotika:

Daar is verskeie teorieë rakende die werkingsmechanisme van probiotika.

Die volgende drie kategorieë is geïdentifiseer:

a. Modulasie van die gaseher se immunspons

Help om die immunsisteem se reaksie teen skadelike bakteriee in die gastrointestinale kanal te bevorder en te verwerk.

b. Versterkte funksie van die epitheellaag

Help om 'n gesonde dermoering te verseker, wat indringing van skadelike bakteriee verhoed.

c. Antimikrobiële effekte

Help voorkom dat bakteriee aan die dermoering vasheg of dit deurdring.

2) Beta 1,3 Glukaan:

Beta-glukaan moduleer of aktiever maar stimuleer nooit die immuunstelsel nie.

3) Zingiber officinale:

'n Hoogs krugtige antioksidant en anti-inflammatoriiese middel wat help om die gladde spiere in die maagvoering te verslap en help met spysvertering wat 'n gesonde derm bevoerd, gastrointestinale pyn verlig, daarheid verlig en die genesi van maagsere fisilliter.

4) Perilla Blaar Ekstrak:

In menslike in vitro- en ex vivo-studies word getoon:

Dit help met die verbetering van gatrointestinale symptome soos opgeblaasheid, windigerheid, volheid en abdominale ongemak

Ondersteun spysverteringsgesondheid

Help met die vervoer van voedsel deur jou derm

Help om 'n normale inflammatoriiese reaksie in jou derm te ondersteun

Help om daagliks gereeldheid te verbeter

En die werking daarvan lyk asof dit met jou neurologiese sisteem in wisselwerkking is en die effek van stres en ander psigososiale faktore te werkendeur jou maag-brein-een.

5) Folien suur: Is 'n groep wateroplosbare B-vitamene wat help om geen-ekspressoie te beheer en te beskermt teen skelemselle wat kanker vermeerder. Omdat die maagwand voortdurend heru word, aangesien nuwe selle na die oppervlak gestoot word en ou selle in jou spysverteringskanal afgebreek word, benodig jy voedingstowwe om hierdie replisieringsproses te beskermt. Folate help om inflamasié te beheer,

6) Vitamien D3: Vitamien D3 is 'n vetoplosbare vitamien. Vitamien D- tekort is gekoppel aan 'n aantal dermafwykings, insluitend:

Dikdermkanker

Diverciculitis

Inflammatoriiese dermsiekte

Prikkelbare derm-syndroom (PDS)

Vitamien B3 is ook as 'n anti-bakteries in die ingewande en voorkom infeksie.



PASIENTINLIGTINGSPAMFLET

SKEDULERINGSTATUS

Ongeskeduleer

HANDELSNAAM EN DOSEERVORM

PROGAST FLORACARE FORTE Kapsules

LEES ASSEBLEEF HIERDIE INLIGTINGSBLAADJIE IN SY GEHEEL SORGVULDIG DEUR, AANGESEN DIT BELANGRIKE INLIGTING VIR JOU BEVAT

PROGAST FLORACARE FORTE is sonder 'n doktersvoorskrif beskikbaar vir jou om in ligte aandoening te behandel. Jy moet nogtans, ten einde die beste resultate daaruit verkry, PROGAST FLORACARE FORTE versigtig gebruik.

Hou hierdie blaaadjie. Jy sal dit daar weer wil deurlees.

Moenie PROGAST FLORACARE FORTE met enige ander persoon deel nie.

Raadpleeg jou apteker indien jy verdere inligting of raad nodig het.

Indien jou simptome vererger of nie binne 30 dae verbeter nie, moet jy 'n dokter raadpleeg.

WAT PROGAST FLORACARE FORTE BEVAT

Bestanddele

Probiotika 4 soorte

Lactobacillus acidophilus

Bifidobacterium longum

Bifidobacterium bifidum

Bifidobacterium lactis

Mangaan AAC 10%

(gelykstaande aan 1 mg elementaal Mangaan)

Selenium AAC 0,2%

(gelykstaande aan 0,02 mg (20 µg) elementaal Selenium)

Sink Glukonaat

(gelykstaande aan 4,9 mg elementaal Sink)

Beta 1,3 glukaan

Vitamien D3

(gelykstaande aan 12,5 µg cholecalciferol)

Zingiber officinale (Gemmer ekstrak)

(wortel, ekstrak standaard aan gingerol 5%)

Perilla frutescens (Perilla blaar ekstrak)

(blaar ekstrak, as 100 mg van 'n 5:1 ekstrak)

Foliensuur (Vitamien B9)

K.V.E.=Kolonie Vormende ten tye van vervaardiging.

WARVOOR PROGAST FLORACARE GEBRUIK WORD

Dit help om die balans van natuurlike Flora te herstel in toestande soos diarree, reisigersdiarree en antibiotikaverwante diarree.

Help om die duur en erns van diarree te verminder

Help om die voorkoms en erns van reisigersdiarree te verminder

Help om die intestinale flora tydens antibiotikaterapie te herstel en onderhou

Help om die voorkoms en duur van antibiotika-geassosieerde diarree te verminder

Versterk die beskermtende skans van die spysverteringskanal

Verbeter spysvertering

Help met algemene dermgesondheid

Help om die simptome wat verband hou met Prikkelbare Derm Sindroom (PDS) te verlig

Help om die simptome van abdominale ongemak, pyn en dermkrampe, geassosieerde spysverteringsprobleme, te verlig

Help om opgeblaasheid en windigerheid te verlig

Verbeter spysvertering

Versterk die beskermtende skans van die spysverteringskanal

Mg per Kapsule: = 5 biljoen KVEs

10 mg

10 mg

35 mg

50 mg

500 IU

150 mg

50 mg

500 IU

500 mg

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