



English

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

Progest® Butyrate Complex

Strength
585,5 mg per capsule

Pharmaceutical form
Solid, DR® delayed-release oral capsule

Active substances

Butyric acid.....	300 mg
L-Glutamine	200 mg
Calcium hydroxide	40 mg
Zinc gluconate.....	25 mg
Magnesium hydroxide	20 mg
Copper bisglycinate.....	0,5 mg

Sugar-free:

- Does not contain sugar or 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® Butyrate Complex 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® Butyrate Complex capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Progest® Butyrate Complex 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

- What Progest® Butyrate Complex capsules is and what it is used for.
- What you need to know before you use Progest® Butyrate Complex capsules.
- How to take Progest® Butyrate Complex capsules.
- Possible side effects.
- How to store Progest® Butyrate Complex capsules.
- Contents of the pack and other information.

1. What Progest® Butyrate Complex capsules is and what it is used for.

This product promotes digestive health and support overall well-being with a unique blend of Butyric acid, L-Glutamine, Calcium hydroxide, Zinc gluconate, Magnesium hydroxide, and Copper bisglycinate.

Due to the active substances, Progest® Butyrate Complex capsules are indicated for therapeutic use only from the age of 18 years and older. These active substances are useful for symptomatic relief of mild digestive discomfort such as bloating, gas, and occasional indigestion by supporting the digestive and gastrointestinal system, promoting healthy colon wall integrity. Its active substances may also support bone health, nerve function, and muscle contraction. It supports the immune system, promotes healthy skin, aids in wound healing. It also supports those who are asymptomatic as a low-risk health supplement and can be used to maintain healthy mineral balance.

It is a health supplement that contains important properties aiding in nutrient absorption, and supporting overall well-being. It be used to support the microbiome, gut-brain axis, and acts as a source of nutrients to healthy bacteria in the small intestine. The unique DR capsules (delayed release) ensure targeted delivery of the key ingredients for the greatest possible effectiveness. Progest® Butyrate Complex 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. When using Progest® Butyrate Complex capsules for maintenance therapy, it is specifically indicated for the purposes of maintaining healthy levels of its key ingredients and is not indicated for alternative maintenance therapy.

It is not indicated as a cure-all or mono therapy for serious conditions because Progest® Butyrate Complex capsules are not intended (nor indicated) to diagnose, treat, prevent, or cure diseases. It is strictly indicated for symptomatic relief as a low-risk supportive supplement.

2. What you need to know before you use Progest® Butyrate Complex capsules.

Do not take Progest® Butyrate Complex capsules:

- if you are hypersensitive (allergic) to the active substances, or any of the other ingredients Progest® Butyrate Complex capsules (listed in section 6).
- without consulting your healthcare provider if you have an existing treatment regimen (see "Warnings and precautions").

Warnings and precautions

Special care should be taken with Progest® Butyrate Complex capsules:

- 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 as this medicine may activate the antibodies that trigger autoimmune responses in those special populations.
- when pregnant or breastfeeding because safety during pregnancy and lactation has not been established.

Children

Do not give Progest® Butyrate Complex capsules to children who are below the age of 18 years because it is unlikely to be safe. Do not attempt to modify the composition of the capsules. Keep out of the reach of children.

Other medicines and Progest® Butyrate Complex capsules

Always tell your health care provider if you are taking any other medicine. Other may interfere with or potentiate the effects of Progest® Butyrate Complex capsules and vice versa.

Progest® Butyrate Complex capsules with alcohol

We do not recommend that you use Progest® Butyrate Complex capsules with alcohol as this may only further impair the benefits that can be derived from 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® Butyrate Complex 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® Butyrate Complex capsules contains the following excipients:

- Microcrystalline cellulose
- Magnesium stearate

3. How to take Progest® Butyrate Complex capsules.

Do not share medicines prescribed for you with any other person. Always take Progest® Butyrate Complex 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.

- The usual dose is 1 to 2 capsules, once daily for **adults 18 years or older**; and is the maximum recommended daily and/or total dose.
- Each dose must be taken or given with a sufficient quantity of liquid (preferably a glass of room temperature water) to ensure safe and proper swallowing/intake of each capsule.
- Take this product orally only.

If you take more Progest® Butyrate Complex capsules than you should

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

If you forget to use Progest® Butyrate Complex 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® Butyrate Complex capsules can have side effects. Not all side effects reported for Progest® Butyrate Complex capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Progest® Butyrate Complex capsules, please consult your health care provider for advice. If any of the following happens, stop taking/using Progest® Butyrate Complex 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® Butyrate Complex 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® Butyrate Complex capsules.

5. How to store Progest® Butyrate Complex 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® Butyrate Complex 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® Butyrate Complex 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® Butyrate Complex capsules looks like and contents of the pack

Progest® Butyrate Complex capsules come in cartons of 30 capsules within blister packs of 10 capsules each for added hygienic use. The blister packs are the primary packaging containing the name markings of the product on the outer foil. Progest® Butyrate Complex capsules has a delayed-release capsule dosage form with a specific appearance: white, fully opaque, 23 mm lock-length, no markings on the capsule. The carton acts as the secondary packaging for storage, also showing the proper labeling on the carton.

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

Progast® Butyrate Complex

Krag

585,5 mg per kapsule

Farmaseutiese vorm

Solied, DR® uitgestelde-vrystelling orale kapsule

Active bestanddele

Butariensurr	300 mg
L-Glutamien	200 mg
Kalsiumhidroksied	40 mg
Sinkglukonaat	25 mg
Magnesiumhidroksied	20 mg
Koperbisglisinaat	0,5 mg

Suikervry:

- Bevat nie suiker of versoeters nie.

Hierdie produk is 'n Komplementêre Medisyne, Kategorie D33.7; en word volgens sy dissipline geïdentifiseer as 'n Kombinasieprodukt; 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 u

Progast® Butyrate Complex kapsules is beskikbaar sonder die voorskrif van 'n dokter, sodat u 'n ligte siekte kan behandel of u gesondheid kan handhaaf. Nietemin moet u Progast® Butyrate Complex kapsules steeds versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Miskien moet u dit weer lees.
- Moenie Progast® Butyrate Complex kapsules met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker of 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

- Wat Progast® Butyrate Complex kapsules is en waarvoor dit gebruik word.
- Wat u moet weet voordat u Progast® Butyrate Complex kapsules gebruik.
- Hoe om Progast® Butyrate Complex kapsules te neem.
- Moontlike nuwe-effekte.
- Hoe om Progast® Butyrate Complex kapsules te stoor.
- Inhoud van die pak en ander inligting.

1. Wat Progast® Butyrate Complex kapsules is en waarvoor dit gebruik word.

Hierdie produk ondersteun die gesondheid van die spysverteringsstelsel en ondersteun die algehele welstand met 'n unieke mengsel van Boteriensuur, L-Glutamiene, Kalsiumhidroksied, Sinkglukonaat, Magnesiumhidroksied, en Koperbisglisinaat.

As gevolg van die aktiewe bestanddele word Progast® Butyrate Kompleks kapsules slegs vir terapeutiese gebruik aangedui vir persone van 18 jaar en ouer. Hierdie aktiewe bestanddele is nuttig vir simptomatiese verligting van ligte spysverteringsongemak soos opgeblasing, gasvorming en af en toe indigestie deur die spysverterings- en gastro-intestinale stelsels te ondersteun, en ondersteun die integriteit van 'n gesonde kolonwand. Die aktiewe bestanddele kan ook die gesondheid van die bene, senuweefsel-funksie en spierkontrakisie ondersteun. Dit ondersteun die immuunstelsel, bevorder gesonde vel en help met wondgeneesing. Dit ondersteun ook diegene wat asimptomaties is as 'n lae-risiko gesondheidsaanvulling en kan gebruik word om 'n gesonde mineraalbalans te handhaaf. Dit is 'n gesondheidsaanvulling wat belangrike eienskappe bevat wat help om voedingstowwe te absorbeer en die algehele welstand te ondersteun. Dit kan gebruik word om die mikrobioom en die darm-brein-as te ondersteun en dien as 'n bron van voedingstowwe vir gesonde bakterieë in die dunne darm. Die unieke DR-kapsules (uitgestelde-vrystelling) verseker geteikende aflewering van die belangrikste bestanddele vir die grootst moontlike doeltreffendheid. Progast® Butyrate Kompleks kapsules word aangedui vir selftoediening as 'n lae-risiko gesondheidsaanvulling, alhoewel slegs 'n gesondheidsverskaffer dit kan aandui as 'n aanvullende behandeling by 'n bestaande behandelingskedule vir individuele persone. Dit word nie aangedui as 'n alternatiewe terapie om konvensionele medisyne of enige ander behandelings wat deur 'n gesondheidsverskaffer voorgeskryf word, te vervang nie. Wanneer Progast® Butyrate Kompleks kapsules vir onderhoudsterapie gebruik word, word dit spesifiek aangedui vir die doel om gesonde vlakke van die belangrikste bestanddele te handhaaf en nie vir alternatiewe onderhoudsterapie nie. Dit word nie aangedui as 'n wondermiddel of monoterapie vir ernstige toestande nie, omdat Progast® Butyrate Kompleks kapsules nie bedoel (of aangedui) is om siektes te diagnoseer, behandel, voorkom of genees nie. Dit word streng aangedui vir simptomatiese verligting as 'n lae-risiko ondersteunende gesondheidsaanvulling.

2. Wat u moet weet voordat u Progast® Butyrate Complex kapsules gebruik.

Moenie Progast® Butyrate Complex kapsules neem:

- As u hipersensitief (allergies) is vir die aktiewe bestanddele, of enige van die ander bestanddele Progast® Butyrate Complex kapsules (gelys in Afdeling 6).
- sonder om u gesondheidsorgverskaffer te raadpleeg as u 'n bestaande behandelingsregime het (sien 'Waarskuwings en voorsorgmaatreëls').

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met Progast® Butyrate Complex kapsules:

- As u 'n lewerbesering het omdat dit moontlik nie veilig is om medisyne te gebruik wat nie deur u gesondheidsorgverskaffer voorgeskryf is nie.
- as u 'n outo-immun siekte of afwyking het, aangesien hierdie medisyne die teenliggaampies kan aktiveer wat outo-immunresponsie in daardie spesiale bevolkings veroorsaak.
- wanneer u swanger is of borsvoed omdat veiligheid tydens swangerskap en laktasie nie vasgestel is nie.

Kinders

Moenie Progast® Butyrate Complex kapsules gee aan kinders wat onder die ouderdom van 18 jaar is nie, want dit is onwaarskynlik dat dit veilig sal wees. Moenie probeer om die samestelling van die kapsules te verander nie. Hou buite bereik van kinders.

Ander medisyne en Progast® Butyrate Complex kapsules

Vertel altyd u gesondheidsorgverskaffer as u enige ander medisyne gebruik. Ander kan inmeng met of versterk die effekte van Progast® Butyrate Complex kapsules en omgekeerd.

Progast® Butyrate Complex kapsules met alkohol

Ons beveel nie aan dat u Progast® Butyrate Complex 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

Geen ongewenste effekte op die bestuur en gebruik van masjiene is aangemeld met Progast® Butyrate Complex 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 maatreël waarop 'n medisyne hulle beïnvloed nie.

Progast® Butyrate Complex kapsules bevat die volgende eksipiënte:

- Mikrokristallynesellulose
- Magnesiumstearaat

3. Hoe om Progast® Butyrate Complex kapsules te neem.

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd Progast® Butyrate Complex 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.

- Die gewone dosis is 1 tot 2 kapsules, een keer daagliks vir **volwassenes bō die ouderdom van 18 jaar**; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Elke dosis moet geneem of gegee word met 'n voldoende hoeveelheid vloeistof (verkieklik 'n glas kamertemperatuurwater) om veilige en behoorlike sluk/inname van elke kapsule te verseker.
- Neem hierdie produk slegs mondeliks.

As u meer Progast® Butyrate Complex 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 Progast® Butyrate Complex kapsules te gebruik

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

4. Moontlike nuwe-effekte.

Progast® Butyrate Complex kapsules kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Progast® Butyrate Complex kapsules gerapporteer word, word in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of as u enige onaangename gevolge ervaar terwyl u Progast® Butyrate Complex kapsules neem, raadpleeg asseblief u gesondheidsorgverskaffer vir raad.

As een van die volgende gebeur, hou op om Progast® Butyrate Complex 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 hipersensitieweit vir Progast® Butyrate Complex 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 u dokter of apteker in kennis.

Verslagdoening van nuwe-effekte

As u nuwe-effekte kry, praat met u 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 Progast® Butyrate Complex kapsules te verskaf.

5. Hoe om Progast® Butyrate Complex 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 Progast® Butyrate Complex 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 Progast® Butyrate Complex kapsules bevat

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

Hoe Progast® Butyrate Complex kapsules lyk en inhoud van die pak

Progast® Butyrate Complex kapsules kom in kartonne van 30 kapsules binne blasiepakke van 10 kapsules elk vir ekstra higiëniese gebruik. Die blasiepakke is die primêre verpakking wat die naammerke van die produk op die buiteste foelie bevat. Progast® Butyrate Complex kapsules het 'n uitgestelde-vrystelling kapsule doseervorm met 'n spesifieke voorkoms: wit, volledig ondeursigtig, 23 mm sluitlengte, geen merke op die kapsule nie. Die karton dien as die sekondêre verpakking vir berging, wat ook die regte etikettering op die karton toon.

Houer van Registrasiesertifikaat

Tara Pharmaceuticals (Edms) Bpk
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Aansoeknommer

DCFS-db4f9a
Wet 101/1965

Toegang tot ooreenstemmende professionele inligting

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