



English

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

Progest® Multi-action Drops

Strength

428,32 mg per 1 mL (approximately 20 drops; or 21,42 mg per drop)

Pharmaceutical form

Liquid, tincture drops, oral

Active substances

Slippery elm bark extract	75 mg
Ginger root extract	70 mg
Chamomile flower extract	66,7 mg
Angelica root extract	33,3 mg
Caraway seed extract	33,3 mg
Milk thistle leaf extract	33,3 mg
Lemon balm leaf extract	33,3 mg
Artichoke leaf extract	33,3 mg
Licorice root extract	33,3 mg
Peppermint leaf extract	16,7 mg

Sugar-free:

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

This product is a Complementary Medicine (Category D33.6); and is identified according to its discipline as a Western Herbal Medicine; 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® Multi-action Drops 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® Multi-action Drops carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Progest® Multi-action Drops 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® Multi-action Drops is and what it is used for.
2. What you need to know before you use Progest® Multi-action Drops.
3. How to take Progest® Multi-action Drops.
4. Possible side effects.
5. How to store Progest® Multi-action Drops.
6. Contents of the pack and other information.

1. What Progest® Multi-action Drops is and what it is used for.

These active substances support the digestive system and overall human health. This health supplement is indicated to support gastrointestinal health and symptomatic relief of indigestion, abdominal cramps, nausea, occasional constipation, mild diarrhea, bloating, irritable bowels, and food sensitivity. It is also indicated to support the management of symptoms related to Irritable Bowel Syndrome (IBS). Supporting the gastrointestinal function and the gut-brain axis, it also contributes to healthy acid regulation, anti-inflammatory functions, stomach lining protection, muscle relaxation throughout the body, and the activation of muscles after a good night's rest. It is a health supplement that contains important health benefits that are due to demulcent, emollient, anxiolytic, antioxidant, weight loss, hepatoprotective, and numerous other beneficial properties. Due to the active substances in this product, it is not suitable for those under 1 year of age. Its active substances may also support the digestive function of asymptomatic individuals as a low-risk health supplement and can be used to maintain healthy levels of phytonutrients. Progest® Multi-action Drops 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® Multi-action Drops are not intended (nor indicated) to diagnose, treat, prevent, or cure diseases. It is strictly indicated for symptomatic relief of minor ailments as a low-risk supportive supplement.

2. What you need to know before you use Progest® Multi-action Drops.

Do not take Progest® Multi-action Drops:

- if you are hypersensitive (allergic) to the active substances, or any of the other ingredients Progest® Multi-action Drops (listed in section 6).
- if you are on blood thinning medication since coumarins, contained in Progest® Multi-action Drops 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® Multi-action Drops:

- 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® Multi-action Drops to children below the age of 1 year because it is unlikely to be safe. The recommended dosages are specifically calculated to be safe for persons above the age of 1 year only. Keep out of the reach of children.

Other medicines and Progest® Multi-action Drops

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

Progest® Multi-action Drops with alcohol

We do not recommend that you use Progest® Multi-action Drops 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® Multi-action Drops. 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® Multi-action Drops contains the following excipients:

- Alcohol 31 % v/v

3. How to take Progest® Multi-action Drops.

Do not share medicines prescribed for you with any other person. Always take Progest® Multi-action Drops 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 and children 12 years and older**, the usual dose is 1 mL (approximately 20 drops), 3 times daily; and
- **for children 6–11 years of age**, the usual dose is reduced to 0.75 mL (approximately 15 drops), 3 times daily; and
- **for children 3–5 years of age**, the usual dose is reduced to 0,50 mL (approximately 10 drops), 3 times daily; and
- **for children 1–2 years of age**, the usual dose is reduced to 0,25 mL (approximately 5 drops), 3 times daily; and
- these are the maximum recommended daily and/or total doses.
- Each dose must be taken or given with a sufficient quantity of liquid (preferably a glass of room-temperature water). Dilute the drops in at least 30 to 60 mL of clean, room-temperature water to ensure safe and proper swallowing/intake.
- Only take this product orally.

If you take more Progest® Multi-action Drops 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® Multi-action Drops

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

5. How to store Progest® Multi-action Drops.

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® Multi-action Drops 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® Multi-action Drops 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® Multi-action Drops looks like and contents of the pack

Progest® Multi-action Drops come in bottles of 20 mL, 50 mL, and 100 mL. Progest® Multi-action Drops has a liquid dosage form with a specific appearance: 1 mL (approximately 20 drops; or 21,42 mg per drop, brown liquid containing plant matter (which are prebiotic phytonutrients), in a brown bottle, and the bottle has the product label. 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® 'Multi-action' Druppels

Sterkte

428,32 mg per 1 mL (ongeveer 20 druppels; of 21,42 mg per druppel)

Farmaseutiese vorm

Vloeistof, tinktuur druppels, oraal

Active bestanddele

Rooiell bas ekstrasak.....	75 mg
Gemmer wortel ekstrasak.....	70 mg
Kamille blom ekstrasak.....	66,7 mg
Angelika wortel ekstrasak.....	33,3 mg
Karwy saad ekstrasak.....	33,3 mg
Melkdistel blaar ekstrasak.....	33,3 mg
Sitroenblaar ekstrasak.....	33,3 mg
Artisjok blaar ekstrasak.....	33,3 mg
Soethout wortel ekstrasak.....	33,3 mg
Pepermentblaarekstrasak.....	16,7 mg

Suiker-vry:

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

Hierdie produk is 'n Komplementêre Medisyne (Kategorie D33.6); en word volgens sy dissipline geïdentifiseer as 'n Westerse Kruiemedyne; wat nie deur die Owerhede 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® 'Multi-action' Druppels is beskikbaar sonder 'n voorskrif van 'n dokter, sodat u 'n ligte siekte kan behandel of u gesondheid kan handhaaf. Nietemin moet u Progest® 'Multi-action' Druppels steeds versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Miskien moet u dit weer lees.
- Moenie Progest® 'Multi-action' Druppels met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteaker 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® 'Multi-action' Druppels is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u Progest® 'Multi-action' Druppels gebruik.
3. Hoe om Progest® 'Multi-action' Druppels te neem.
4. Moontlike nuwe-effekte.
5. Hoe om Progest® 'Multi-action' Druppels te stoor.
6. Inhoud van die pak en ander inligting.

1. Wat Progest® 'Multi-action' Druppels is en waarvoor dit gebruik word.

Hierdie aktiewe bestanddele ondersteun die spysverteringsstelsel en algemene menslike gesondheid. Hierdie gesondheidsaanvulling word aangedui om gastro-intestinale gesondheid en simptomatie verligting van spysvertering, buikkramp, naarheid, af en toe hardlywigheid, ligte diarree, opgeblasenheid, prikkelbare ingewande en voedsel sensitiviteit te ondersteun. Dit word ook aangedui om die bestuur van simptome wat verband hou met prikkelbare dermsindroom (IBS) te ondersteun. Ondersteuning van die gastro-intestinale funksie en die derm-brein-as, dra dit ook by tot gesonde suurregulering, anti-inflammatoriese funksies, maagvoeringbeskerming, spierverslapping deur die liggaam en die aktivering van spiere na 'n goeie nagrus. Dit is 'n gesondheidsaanvulling wat belangrike gesondheidsvoordele bevat as gevolg van demulsente, versagtende, anxiolitiese, antioksidante, gewigsverlies, hepatobeskermerende en talle ander voordelige eienskappe. As gevolg van die aktiewe bestanddele in hierdie produk, is dit nie geskik vir diegene jonger as 1 jaar nie. Die aktiewe bestanddele kan ook die spysverteringsfunksie van asimptomaties individue ondersteun as 'n laerisiko-gesondheidsaanvulling en kan gebruik word om gesonde vlakke van fitonutriënte te handhaaf. Progest® Multi-action Drops word aangedui vir selfadministrasie as 'n laerisiko-gesondheidsaanvulling, hoewel slegs 'n gesondheidsorgverskaffer dit kan aandui as 'n addisionele behandeling vir 'n bestaande behandelingsregime vir individuele persone. Dit word nie aangedui as 'n alternatiewe terapie om konvensionele medisyne of enige ander behandelings wat deur 'n gesondheidsorgverskaffer voorgeskryf word, te vervang nie. Dit word nie aangedui as 'n geneesmiddel of monoterapie vir ernstige toestande nie, omdat Progest® Multi-action Drops nie bedoel is (of aangedui word) om siektes te diagnoseer, te behandel, te voorkom of te genees nie. Dit word streng aangedui vir simptomatie verligting van geringe kwale as 'n laerisiko-ondersteunende aanvulling.

2. Wat u moet weet voordat u Progest® 'Multi-action' Druppels gebruik.

Moenie Progest® 'Multi-action' Druppels neem:

- as u hipersensitief (allergies) is vir die aktiewe bestanddele, of enige van die ander bestanddele Progest® 'Multi-action' Druppels (gelys in afdeling 6) nie.
- as u bloedverduunningsmedikasie gebruik nie, aangesien kumariene, vervat in Progest® 'Multi-action' Druppels, reeds 'n bloedverduunningseffek 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® 'Multi-action' Druppels:

- 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-immun siekte of afwyking het, wees waaksaam en versigtig, aangesien hierdie medisyne immuunonderdrukkers kan teenwerk en die immuunsisteem kan versterk.

Kinders

Moenie Progest® 'Multi-action' Druppels aan kinders onder die ouderdom van 1 jaar gee nie, want dit is onwaarskynlik dat dit veilig sal wees. Die aanbevole dosisse word spesifiek

bereken om slegs veilig te wees vir persone bo die ouderdom van 1 jaar. Hou buite bereik van kinders.

Ander medisyne en Progest® 'Multi-action' Druppels

Vertel altyd jou gesondheidsorgverskaffer as u enige ander medisyne gebruik. Ander medisyne kan inmeng met of die effekte van Progest® 'Multi-action' Druppels versterk, en omgekeerd.

Progest® 'Multi-action' Druppels met alkohol

Ons beveel nie aan dat u Progest® 'Multi-action' Druppels 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, apteaker 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 Progest® 'Multi-action' Druppels nie. Dit is nie altyd moontlik om te voorspel in watter 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.

Progest® 'Multi-action' Druppels bevat die volgende ekspiënte:

- Alkohol..... 31 % v/v

3. Hoe om Progest® 'Multi-action' Druppels te neem.

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd Progest® 'Multi-action' Druppels presies soos beskryf in hierdie pamflet of soos u dokter, apteaker of verpleegster u vertel het. Raadpleeg u dokter, apteaker of verpleegster as u nie seker is nie.

- **Vir volwassenes en kinders 12 jaar en ouer** is die gewone dosis 1 mL (ongeveer 20 druppels), 3 keer per dag; en
- **vir kinders van 6-11 jaar** word die gewone dosis verminder tot 0,75 mL (ongeveer 15 druppels), 3 keer per dag; en
- **vir kinders van 3-5 jaar** word die gewone dosis verminder tot 0,50 mL (ongeveer 10 druppels), 3 keer per dag; en
- **vir kinders van 1-2 jaar** word die gewone dosis verminder tot 0,25 mL (ongeveer 5 druppels), 3 keer 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 (verkiel 'n glas kamertemperatuurwater). Verdun die druppels in minstens 30 tot 60 ml skoon, kamertemperatuurwater om veilige en behoorlike sluk/inname te verseker.
- Neem hierdie produk slegs modelings.

As u meer Progest® 'Multi-action' Druppels neem as wat u moet

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

As u vergeet om Progest® 'Multi-action' Druppels 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® 'Multi-action' Druppels kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Progest® 'Multi-action' Druppels gerapporteer word, word in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of as u enige onaangename gevolge ervaar terwyl u Progest® 'Multi-action' Druppels neem, raadpleeg asseblief u gesondheidsorgverskaffer vir raad. As een van die volgende gebeur, hou op om Progest® 'Multi-action' Druppels 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 hipersensitiviteit vir Progest® 'Multi-action' Druppels. 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 apteaker in kennis.

Verslagdoening van nuwe-effekte

As u nuwe-effekte kry, praat met jou dokter, apteaker 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® 'Multi-action' Druppels te verskaf.

5. Hoe om Progest® 'Multi-action' Druppels 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 omgewingsvochtigheid tussen 35 % en 65 %. Moenie verkoel of vries nie. Berg in die oorspronklike verpakking of houer. Beskerm teen direkte sonlig en vog. Moenie dit gebruik na die vervaldatum wat op die etiket aangedui word nie. Moenie Progest® 'Multi-action' Druppels 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 apteaker. Moenie ongebruikte medisyne in dreine of rioelstelsels weggooi nie. Herwin asseblief die leë houers.

6. Inhoud van die pak en ander inligting.

Wat Progest® 'Multi-action' Druppels bevat

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

Hoe Progest® 'Multi-action' Druppels lyk en inhoud van die pak

Progest® 'Multi-action' Druppels kom in bottels van 20 mL, 50 mL en 100 mL. Progest® 'Multi-action' Druppels het 'n vloeibare doseervorm met 'n spesifieke voorkoms: 1 mL (ongeveer 20 druppels; of 21,42 mg per druppel, bruin vloeistof wat plantmateriaal bevat (wat prebiotiese fitonutriënte is), in 'n bruin bottel, en die bottel het die produk-etiket. Die karton dien as die sekondêre verpakking vir berging, wat ook die regte etikettering toon.

Houer van Registrasiesertifikaat

Tara Pharmaceuticals (Pty) Ltd
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Aansoeknommer

DCFS-db49a
Wet 101/1965

Toegang tot ooreenstemmende professionele inligting

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