



English

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

Progest® Proliver Ultra Capsules

Strength
619 mg per capsule

Pharmaceutical form
Solid, hydroxypropyl methylcellulose capsules, oral

Active substances

Milk Thistle seed	200 mg
Artichoke leaf	150 mg
Choline bitartrate	100 mg
Dandelion root	50 mg
Ginger root	50 mg
Triphala	70 mg

Sugar-free:

- Does not contain sweeteners.

This product is 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® Proliver Ultra 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® Proliver Ultra Capsules carefully to get the best results from it.

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

1. What Progest® Proliver Ultra Capsules is and what it is used for.

Progest® Pro-liver Ultra Capsules is for supporting the body to detox by helping provide liver health support, promoting healthy excretions and absorptions while benefitting overall health and wellbeing with hepatotherapeutic effects.

Due to the active substances, Progest® Pro-liver Ultra Capsules are indicated for therapeutic use only from the age of 18 years and older.

The active substances are useful for liver health support and reducing the risk of an unhealthy liver which supports the digestive system. Its active substance choline bitartrate may also support the maintenance of choline levels which play an important role in maintaining overall health and wellness.

It is a health supplement that contains important liver detoxifying properties important in liver cellular repair activities used to support the digestive system, supporting the small intestine and colon as a liver health and detox promoting supplement.

Progest® Pro-liver Ultra 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.

Progest® Pro-liver Ultra Capsules is a medicinal health supplement not intended (nor indicated) for alternative maintenance therapy, but rather for symptomatic relief from a liver in need of support with this medicine and to promote liver health and liver detox. It is not indicated as a cure-all or monotherapy for serious conditions because Progest® Pro-liver Ultra Capsules is not intended (nor indicated) to diagnose, treat, prevent, or cure diseases. It is strictly indicated for symptomatic relief and to promote liver health and liver detox as a low-risk supportive supplement.

2. What you need to know before you use Progest® Proliver Ultra Capsules.

Do not take Progest® Proliver Ultra Capsules:

- if you are hypersensitive (allergic) to the active substances, or any of the other ingredients Progest® Proliver Ultra Capsules (listed in section 6).
- if you are on morphine medication since Progest® Proliver Ultra Capsules may interfere with the activity of morphine (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® Proliver Ultra Capsules:

- if you are already on antidiabetic medication because of the antidiabetic properties and glycemic effects of the active ingredients in Progest® Proliver Ultra Capsules.
- when pregnant or breastfeeding because safety during pregnancy and lactation has not been established.

Children

Do not give Progest® Proliver Ultra 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 capsule. 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® Proliver Ultra Capsules

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

Progest® Proliver Ultra Capsules with alcohol

We do not recommend that you use Progest® Proliver Ultra 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® Proliver Ultra 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® Proliver Ultra Capsules contains the following excipients:

- Microcrystalline cellulose
- Magnesium stearate
- Silicon dioxide

3. How to take Progest® Proliver Ultra Capsules.

Do not share medicines prescribed for you with any other person. Always take Progest® Proliver Ultra 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 capsule, 3 times daily for people over 18 years of age; 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.
- Only take this product orally.

If you take more Progest® Proliver Ultra 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® Proliver Ultra 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® Proliver Ultra Capsules can have side effects. Not all side effects reported for Progest® Proliver Ultra Capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Progest® Proliver Ultra Capsules, please consult your health care provider for advice.

If any of the following happens, stop taking/using Progest® Proliver Ultra 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® Proliver Ultra 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® Proliver Ultra Capsules.

5. How to store Progest® Proliver Ultra 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® Proliver Ultra 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® Proliver Ultra 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® Proliver Ultra Capsules looks like and contents of the pack

Progest® Proliver Ultra Capsules may come in blister packs of 10 capsules or zip-lock sachets of 3 capsules each, as the primary packaging. Progest® Proliver Ultra Capsules has a capsule dosage form with a specific appearance: Capsule, hard gelatin, white and yellow, 21.6mm lock length, and no markings. 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® Proliver Ultra Kapsules

Sterkte
619 mg per kapsule

Farmaseutiese vorm
Solied, hidroksiemetielcellulose kapsules, orale

Aktiewe bestanddele

Melkdistelsaad	200 mg
Artisjok blaar	150 mg
Cholien bitartraat	100 mg
Paardebloemwortel	50 mg
Gemmer wortel	50 mg
Triphala	70 mg

Suikervry:

- Bevat nie versoeters nie.

Hierdie produk is 'n Komplimentêre Medisyne (Kategorie D33.7); en word geïdentifiseer volgens sy dissipline as 'n Kombinasie Produk; which is not registered by the Owerheid.

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

Lees hierdie hele pamflet noukeurig deur omdat dit belangrike inligting vir u bevat

Progest® Proliver Ultra Kapsules is beskikbaar sonder 'n dokter se voorskrif, sodat jy 'n ligte siekte kan behandel of jou gesondheid kan handhaaf. Maar jy moet nog steeds Progest® Proliver Ultra Kapsules ernstig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Miskien moet jy dit weer lees.
- Moenie Progest® Proliver Ultra Kapsules deel met enige ander persoon nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies nodig het.
- U moet 'n dokter sien as u simptome vererger of nie na 7 dae verbeter nie.

Wat is in hierdie pamflet

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

1. Wat Progest® Proliver Ultra Kapsules is en waarvoor dit gebruik word.

Progest® Pro-liver Ultra Kapsules is vir die ondersteuning van die liggaam om te detoks deur te help om lewer gesondheidsondersteuning te bied, gesonde uitskeidings en absorpsies te bevorder, terwyl algehele gesondheid en welstand bevoordeel word met hipnoterapeutiese effekte. As gevolg van die aktiewe stowwe word Progest® Pro-liver Ultra Kapsules slegs vanaf die ouderdom van 18 jaar en ouer vir terapeutiese gebruik aangedui. Die aktiewe stowwe is nuttig vir lewergesondheidsondersteuning en die vermindering van die risiko van 'n ongesonde lewer wat die spysverteringstelsel ondersteun. Die aktiewe bestanddele cholien bitartrate kan ook die instandhouding van cholienvlakke ondersteun wat 'n belangrike rol speel in die handhawing van algemene gesondheid en welstand. Dit is 'n gesondheidsaanvulling wat belangrike lewerontgiftingseienskappe bevat wat belangrik is in lewer sellulêre herstelaktiwiteit wat gebruik word om die spysverteringstelsel te ondersteun, wat die dunderm en dikderm ondersteun as 'n lewergesondheid en detoksbevorderende aanvulling. Progest® Pro-liver Ultra Kapsules 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. Progest® Pro-liver Ultra Kapsules is 'n medisinale gesondheidsaanvulling wat nie bedoel is (of aangedui word) vir alternatiewe instandhoudingsterapie nie, maar eerder vir simptomatiese verligting van 'n lewer wat ondersteuning met hierdie medisyne benodig en lewergesondheid en lewerdetoks bevorder. Dit word nie aangedui as 'n geneesmiddel of monoterapie vir ernstige toestande nie, omdat Progest® Pro-liver Ultra Kapsules nie bedoel is (of aangedui word) om siektes te diagnoseer, te behandel, te voorkom of te genees nie. Dit word streng aangedui vir simptomatiese verligting en om lewergesondheid en lewerdetoks te bevorder as 'n laerisiko-ondersteunende aanvulling.

2. Wat jy moet weet voordat jy Progest® Proliver Ultra Kapsules gebruik.

Moenie Progest® Proliver Ultra Kapsules neem:

- as jy hipersensitief (allergies) is vir die aktiewe stowwe, of enige van die ander bestanddele Progest® Proliver Ultra Kapsules (gelys in afdeling 6) nie.
- as jy op morfin medikasie is nie sedert die aktiewe bestanddele vervat in Progest® Proliver Ultra Kapsules 'n interaksie het daarmee (sien 'Waarskuings en voorsorgmaatreëls').
- as u 'n operasie of tandheelkundige prosedure geskeduleer het nie, vir ten minste twee weke voor dit.
- sonder om u gesondheidsorgverskaffer te raadpleeg as u 'n bestaande behandelingsregime het nie.

Waarskuings en voorsorgmaatreëls

Spesiale sorg moet geneem word met Progest® Proliver Ultra Kapsules:

- as jy reeds op anti-diabetiese medikasie is as gevolg van die anti-diabetiese en glukemiese eienskappe van die aktiewe bestanddele.
- wanneer jy swanger is of borsvoed omdat veiligheid tydens swangerskap en laktasie nie vasgestel is nie.

Kinders

Moenie Progest® Proliver Ultra Kapsules aan mense onder die ouderdom van 18 jaar gee nie, want dit is onwaarskynlik dat dit veilig sal wees. Moenie probeer om die samestelling van die kapsules te verander 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® Proliver Ultra Kapsules

Sê altyd vir jou gesondheidsorgverskaffer as jy enige ander medisyne neem. Anders kan Progest® Proliver Ultra Kapsules saam met ander medisyne inmengende of versterkte effekte hê.

Progest® Proliver Ultra Kapsules met alkohol

Ons beveel nie aan dat u Progest® Proliver Ultra Kapsules met alkohol gebruik nie, aangesien dit slegs die voordele wat uit die aktiewe bestanddele verkry kan word, 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 asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Bestuur en gebruik van masjiene

Geen ongewenste effekte op die bestuur en gebruik van masjiene is aangemeld met Progest® Proliver Ultra Kapsules nie. Dit is nie altyd moontlik om te voorspel in watter mate 'n medisyne die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate tot wat 'n medisyne hulle beïnvloed nie.

Progest® Proliver Ultra Kapsules bevat die volgende eksipiënte:

- Mikrokristalinesellulose
- Magnesiumsteraat
- Silikoondioksied

3. Hoe om Progest® Proliver Ultra Kapsules te gebruik.

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

- Die gewone dosis is 1 kapsule, 3 keer per dag vir mense ouer as 18 jaar; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Elke dosis moet geneem of gegee word met 'n voldoende hoeveelheid vloeistof (verkieles 'n glas kamertemperatuurwater) om veilig en behoorlike sluk/inname van elke kapsule te verseker..
- Neem slegs hierdie produk mondelings.

As jy meer Progest® Proliver Ultra Kapsules neem as wat jy moet

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

As jy vergeet om Progest® Proliver Ultra Kapsules te gebruik

- moet dan nie die maksimum aanbevole daaglikse en/of totale dosis oorskry nie; en
- moenie 'n dubbele dosis gebruik om op te maak vir vergete individuele dosisse nie.

4. Moontlike nuwe-effekte.

Progest® Proliver Ultra Kapsules Kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Progest® Proliver Ultra Kapsules gerapporteer word, word in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige gevolge ervaar terwyl jy Progest® Proliver Ultra Kapsules neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies. As enige van die volgende gebeur, hou op om Progest® Proliver Ultra Kapsules te neem/gebruik en vertel u dokter onmiddellik of gaan na die ongevalle-afdeling of u naaste hospitaal:

- 'swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal',
- 'uitslag of jeuk',
- 'floute'

Dit is alles baie ernstige nuwe-effekte en kan tekens wees van 'n allergiese reaksie of hipersensitiewiteit vir Progest® Proliver Ultra Kapsules. Miskien het u dringende mediese hulp of hospitalisasie nodig. As u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet u jou dokter of apteker in kennis stel.

Verslagdoening van nuwe-effekte

As u nuwe-effekte kry, praat dan 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 onder SAHPRA se publikasies gevind word: <https://www.sahpra.org.za/Publications/Index/8>. Deur verslagdoening van nuwe-effekte, kan jy help om meer inligting oor die veiligheid van Progest® Proliver Ultra Kapsules.

5. Hoe om Progest® Proliver Ultra Kapsules te stoor.

Stoor alle medisyne buite bereik van kinders. Stoor in 'n koel, droë plek by temperature van 59-77° F, gelykstaande aan 15-25° C, en met omgewingsvogtigheid tussen 35% en 65%. Moenie verkoel of vries nie.

Stoor in die oorspronklike pakket of houër.

Beskerm teen direkte sonlig en vog.

Moenie dit gebruik na die vervaldatum wat op die etiket aangedui is nie.

Moenie Progest® Proliver Ultra Kapsules gebruik as jy 'n abnormale voorkoms of onaangename reuk opmerk nie, aangesien die produk moontlik vervat het of onbehoorlik gestoor was.

Gee alle ongebruikte medisyne aan u apteker terug.

Moenie ontslae raak van ongebruikte medisyne in dreine of rioolstelsels nie.

Herwin asseblief die leë houers.

6. Inhoud van die pak en ander inligting.

Wat Progest® Proliver Ultra Kapsules bevat

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

Hoe Progest® Proliver Ultra Kapsules lyk en inhoud van die pak

Progest® Proliver Ultra Kapsules kan kom in blasepakke van 10 kapsules of ritsslotsakkies van 3 kapsules elk, as die primêre verpakking. Progest® Proliver Ultra Kapsules het 'n kapsule dosis vorm met 'n spesifieke voorkoms: Kapsule, harde gelatien, wit en geel, 21.6mm slot lengte, en geen merke. Die karton dien as die sekondêre verpakking vir berging, wat ook die regte etikettering toon.

Houer van Registrasiesertifikaat

Tara Pharmaceuticals (Edms) Bpk

36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

Aansoeknommer

DCFS-db4f9a

Wet 101/1965

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