



English

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:**

S0

InoLax® Forte Capsules

Strength
665 mg per capsule

Pharmaceutical form
Solid, hydroxypropyl methylcellulose capsules, oral

Active substances

| | |
|---------------------------|--------|
| Cape Aloe leaf | 180 mg |
| Potassium Chloride | 100 mg |
| Magnesium Oxide | 80 mg |
| Cascara bark powder | 80 mg |
| Senna leaf | 70 mg |
| Fennel seed | 60 mg |
| Dandelion root | 35 mg |
| Rhubarb root | 30 mg |
| Apple pectin | 25 mg |
| Ginger root | 5 mg |

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

InoLax® Forte 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 InoLax® Forte Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share InoLax® Forte 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 2 days.

What is in this leaflet

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

1. What InoLax® Forte Capsules is and what it is used for.

InoLax® Forte Capsules is for supporting the body to detox by helping relieve occasional constipation and stimulating bowel movement while benefitting overall health and wellbeing with a therapeutic antioxidant effect. Due to the active substances, InoLax® Forte Capsules are indicated for therapeutic use only from the age of 18 years and older. The active substances are useful for symptomatic relief of occasional constipation by supporting the digestive system. Its active substance potassium chloride may also support the maintenance of potassium levels given the laxative effect. It is a health supplement that contains important bowel stimulating and antioxidant properties and can be used to support the digestive system, supporting the small intestine and colon as a herbal laxative. InoLax® Forte 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. InoLax® Forte Capsules is a medicinal health supplement not intended (nor indicated) for maintenance or alternative maintenance therapy, but rather for symptomatic relief when this medicine is needed. It is not indicated as a cure-all or monotherapy for serious conditions because InoLax® Forte Capsules is 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 InoLax® Forte Capsules.**Do not take InoLax® Forte Capsules:**

- if you are hypersensitive (allergic) to the active substances, or any of the other ingredients InoLax® Forte Capsules (listed in section 6).
- if you are on heart medication to treat arterial fibrillation, heart flutter, or heart failure (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 InoLax® Forte Capsules:

- if you are already on heart medication because of the risk of a likely interaction between heart medications and herbal laxatives which is based on theoretical pharmacology.
- when pregnant or breastfeeding because safety during pregnancy and lactation has not been established.

Children

Do not give InoLax® Forte 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. 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 InoLax® Forte Capsules

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

InoLax® Forte Capsules with alcohol

We do not recommend that you use InoLax® Forte 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 InoLax® Forte 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.

InoLax® Forte Capsules contains the following excipients:

- Magnesium stearate

3. How to take InoLax® Forte Capsules.

Do not share medicines prescribed for you with any other person. Always take InoLax® Forte 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, 2 times daily, or 2 capsules, 1 time daily, for no longer than 10 days, for **adults over the age of 18 years**; 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 InoLax® Forte 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 InoLax® Forte 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.

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

If any of the following happens, stop taking/using InoLax® Forte 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 InoLax® Forte 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 InoLax® Forte Capsules.

5. How to store InoLax® Forte 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 InoLax® Forte 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 InoLax® Forte 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 InoLax® Forte Capsules looks like and contents of the pack

InoLax® Forte Capsules may come in blister packs of 10 capsules per blister inside of cartons containing 1, 2, or 3 blister packs. The active substances provide a total of 665 mg per capsule.

InoLax® Forte Capsules has a capsule dosage form with a specific appearance: Solid, hydroxypropyl methylcellulose capsules, transparent, 23.4 mm lock-length, 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

Inolax® Forte Kapsules**Sterkte**

665 mg per capsule

Farmaseutiese vorm

Soliede, hydroxypropyl methylcellulose kapsules, orale

Aktiewe bestanddele

| | |
|--------------------------|--------|
| Kaapse Aalwynblaar | 180 mg |
| Kaliumchloried | 100 mg |
| Magnesiumoksied | 80 mg |
| Cascara bas poeier | 80 mg |
| Senna blaar | 70 mg |
| Vinkel saad | 60 mg |
| Paardebloem wortel | 35 mg |
| Rabarber wortel | 30 mg |
| Appel pektien | 25 mg |
| Gemmerwortel | 5 mg |

Suikervry:

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

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

Hierdie ongeregistreerde 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

Inolax® Forte 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 Inolax® Forte Kapsules ernstig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Miskien moet jy dit weer lees.
- Moenie Inolax® Forte 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 Inolax® Forte Kapsules is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy Inolax® Forte Kapsules gebruik.
3. Hoe om Inolax® Forte Kapsules te neem.
4. Moontlike nuwe-effekte.
5. Hoe om Inolax® Forte Kapsules te stoor.
6. Inhoud van die pak en ander inligting.

1. Wat Inolax® Forte Kapsules is en waarvoor dit gebruik word.

Inolax® Forte Kapsules is vir die ondersteuning van die liggaam om te detoks deur hardlywigheid te verlig en derm beweging te stimuleer, terwyl die voordeel algehele gesondheid en welstand met 'n terapeutiese antioksidant effek ondersteun. As gevolg van die aktiewe bestanddele word Inolax® Forte Kapsules slegs aangedui vir terapeutiese gebruik vanaf die ouderdom van 18 jaar en ouer. Die aktiewe bestanddele is nuttig vir simptomiese verligting van af en toe hardlywigheid deur die spysverteringstelsel te ondersteun. Die aktiewe bestanddeel kaliumchloried kan ook die instandhouding van kaliumvlakke ondersteun gegewe die lakseermiddel. Dit is 'n gesondheidsaanvulling wat belangrike dermstimulerende en antioksidante eienskappe bevat en kan gebruik word om die spysverteringstelsel te ondersteun, wat die dunderm en dikderm as 'n kruielakseermiddel ondersteun. Inolax® Forte Kapsules word aangedui vir selfadministrasie as 'n lae-risiko gesondheidsaanvulling, hoewel slegs 'n gesondheidsorgverskaffer dit kan aandui as 'n byvoeglike behandeling vir 'n bestaande behandelingsregime vir individuele persone. Dit word nie aangedui as 'n alternatiewe terapie om konvensionele medisyne nie of om enige ander behandelings wat deur 'n gesondheidsorgverskaffer voorgeskryf word, te vervang nie. Inolax® Forte Kapsules is 'n medisinale gesondheidsaanvulling wat nie bedoel (of aangedui) is vir instandhouding of alternatiewe instandhoudingsterapie nie, maar eerder vir simptomiese verligting wanneer hierdie medisyne nodig is. Dit word nie aangedui as 'n geneesmiddel of monoterapie vir ernstige toestande nie omdat Inolax® Forte Kapsules nie bedoel (of aangedui) is om siektes te diagnoseer, te behandel, te voorkom of te genees nie. Dit word streng aangedui vir simptomiese verligting as 'n lae-risiko ondersteunende aanvulling.

2. Wat jy moet weet voordat jy Inolax® Forte Kapsules gebruik.**Moenie Inolax® Forte Kapsules neem:**

- as jy hipersensitief (allergies) is vir die aktiewe bestanddele nie, of enige van die ander bestanddele in Inolax® Forte Kapsules (gelys in afdeling 6).
- as jy op hartmedikasie is om arteriële fibrillasie, hartfluit of hartversaking te behandel nie (sien 'Waarskuwings 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.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met Inolax® Forte Kapsules:

- as jy reeds op hartmedikasie is as gevolg van die risiko van 'n waarskynlike interaksie tussen hartmedikasie en kruie-lakseermiddels wat gebaseer is op teoretiese farmakologie.
- wanneer u swanger is of borsvoed omdat veiligheid tydens swangerskap en laktasie nie vasgestel is nie.

Kinders

Moenie Inolax® Forte Kapsules aan kinders wat 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 Inolax® Forte Kapsules

Sê altyd vir jou gesondheidsorgverskaffer as jy enige ander medisyne neem. Anders kan die gevolge van Inolax® Forte Kapsules asook ander medisyne inmengende of versterkte effekte hê.

Inolax® Forte Kapsules met alkohol

Ons beveel nie aan dat u Inolax® Forte 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 Inolax® Forte 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.

Inolax® Forte Kapsules bevat die volgende ekspiënte:

- Magnesiumstearaat

3. Hoe om Inolax® Forte Kapsules te gebruik.

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem altyd Inolax® Forte 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, 2 keer per dag, of 2 kapsules, 1 keer per dag, vir nie meer as 10 dae nie, vir **volwassenes 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 (verkieklik 'n glas kamertemperatuurwater) om veilige en behoorlike sluk/innam van elke kapsule te verseker.
- Neem hierdie produk slegs mondlig.

As jy meer Inolax® Forte 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 Inolax® Forte 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.

Inolax® Forte Kapsules Kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Inolax® Forte Kapsules gerapporteer word, word in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige gevolge ervaar terwyl jy Inolax® Forte Kapsules neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, hou op om Inolax® Forte Kapsules te neem/gebruik en vertel u dokter onmiddellik of gaan na die ongevallende afdeling by 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 Inolax® Forte 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 Inolax® Forte Kapsules.

5. Hoe om Inolax® Forte 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 houer.

Beskermt teen direkte sonlig en vog.

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

Moenie Inolax® Forte Kapsules gebruik as jy 'n abnormale voorkoms of onaanname reuk opmerk nie, aangesien die produk moontlik vervul het of onbehoorlik gestoor was.

Gee alle ongebruikte medisyne aan u apteker terug.

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

Herwin asseblief die leë houers.

6. Inhoud van die pak en ander inligting.**Wat Inolax® Forte Kapsules bevat**

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

Hoe Inolax® Forte Kapsules lyk en inhoud van die pak

Inolax® Forte Kapsules kan kom in blasiepakke van 10 kapsules per blasiepak binne-in kartonne wat 1, 2, of 3 blasiepakke bevat. Die aktiewe bestanddele bied 'n totaal van 665 mg per kapsule.

Inolax® Forte Kapsules het 'n kapsule dosis vorm met 'n spesifieke voorkoms: Solied, hidroksielmetiellselulose kapsules, deursigtig, 'n 23.4 mm slotlengte, geen merke. Die karton dien as die sekondêre verpakking vir berging, wat ook die regte etikettering toon.

Houer van Registrasiesertifikaat

Tara Pharmaceuticals (Pty) Ltd

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

Aansoeknommer

DCFS-db49a

Wet 101/1965

Toegang tot ooreenstemmende Professionele Inligting

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