

# Prokast

## GASTROINTESTINAL SUPPORT

**PROGAST**  
ORAL LIQUID

**SCHEDULING STATUS**  
S0

### COMPOSITION

Each 20 drops (1 ml) contains:

<i>Ulmus rubra</i> Muh. (Slippery elm bark)	75,0 mg
<i>Zingiber officinale</i> L. (Ginger root)	70,0 mg
<i>Matricaria chamomilla</i> L. (German chamomile flower)	66,7 mg
<i>Angelica archangelica</i> L. (Angelica root)	33,3 mg
<i>Carum carvi</i> L. (Caraway fruit)	33,3 mg
<i>Silybum marianum</i> (L.) Gaertn. (Milk thistle fruit)	33,3 mg
<i>Melissa officinalis</i> L. (Lemon balm leaf)	33,3 mg
<i>Cynara scolymus</i> L. (Artichoke leaf)	33,3 mg
<i>Glycerhiza glabra</i> L. (Licorice root)	33,3 mg
<i>Mentha piperita</i> L. (Peppermint leaf)	16,7 mg

Contains alcohol 31 % v/v

### CATEGORY AND CLASS

Category D.11.1 Digestants  
Complementary Medicine. Western Herbal.

### PHARMACOLOGICAL ACTION

#### Pharmacodynamic properties:

The 10 herbal extracts used in **PROGAST** have all been traditionally used to relieve symptoms of gastric and abdominal discomfort.

#### Pharmacokinetic properties:

The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted on **PROGAST**.

### INDICATIONS

To reduce symptoms related to gastric and abdominal discomfort like:

- Abdominal Pain & Cramps
- Heartburn
- Bloating & Flatulence
- Chronic Constipation
- Nausea
- Irritable Bowel Syndrome (IBS)

### CONTRAINDICATION

Hypersensitivity to any of the ingredients of **PROGAST** or hypersensitivity to the *Asteraceae* or *Compositae* families.

### WARNINGS AND SPECIAL PRECAUTIONS

Patients with pre-existing liver disease should consult with their doctor before starting treatment on **PROGAST**.

#### Effects on the ability to drive and use machinery:

No studies on the effect of **PROGAST** on the ability to drive or operate machinery were performed. It is unlikely that **PROGAST** would affect the ability to drive or operate machinery.

### INTERACTIONS

There are no known interactions with other medicines. Patients affected with serious chronic diseases and/or undergoing medical treatment should take **PROGAST** under medical guidance. **PROGAST** may be taken by diabetics.

### HUMAN REPRODUCTION

#### Pregnancy and lactation

The use of **PROGAST** during pregnancy and lactation has not been fully studied and it should only be used in these circumstances under the guidance of a healthcare professional.

### DOSAGE AND DIRECTIONS FOR USE

**Adults and children over 12 years:**

Take 20 drops (1,0 ml) 3 times a day.

**Children 6 to 12 years:**

Give 15 drops (0,75 ml) 3 times a day.

**Children 3 to 5 years:**

Give 10 drops (0,5 ml) 3 times a day.

**Children 3 months to 3 years:**

Give 8 drops (0,4 ml) 3 times a day.

**Infants under 3 months:**

Give 6 drops (0,3 ml) 3 times a day.

*Children and infants under 3 years to use PROGAST under supervision of a medical healthcare professional: not to be used for longer than 7 (seven) consecutive days in infants under 1 (one) year.*

**SHAKE THE BOTTLE BEFORE USE.** Remove the white screw cap, turn the bottle upside down, and hold at an angle of 45° and give a slight shake. Count the number of drops and mix with a small quantity (30-60 ml) of room temperature water. **PROGAST** should be taken before or with meals, three times a day.

### SIDE EFFECTS

#### *Angelica archangelica* L.

Photosensitivity (*frequency unknown*).

#### *Matricaria chamomilla* L.

Hypersensitivity reactions including anaphylaxis (*frequency unknown*).

#### *Silybum marianum* (L.) Gaertn.

Mild gastrointestinal symptoms such as dry mouth, nausea, upset stomach, gastric irritation and diarrhoea may occur; headache; allergic reactions (dermatitis, urticaria, skin rash, pruritus, anaphylaxis, asthma) may occur (*frequency unknown*).

#### *Melissa officinalis* L.

It can cause nausea, vomiting, abdominal pain, dizziness, and wheezing (*frequency unknown*).

#### *Mentha piperita* L.

The gastro-oesophageal reflux may worsen and heartburn may increase (*frequency unknown*).

#### *Zingiber officinale* L.

Minor gastrointestinal complaints, particularly stomach upset, eructation, dyspepsia and nausea have been reported (*frequent*).

### KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF IT'S TREATMENT

No reports of over dosage have been found in the literature on the active ingredients used in **PROGAST**. In cases of suspected over dosage treatment should be symptomatic and supportive.

### IDENTIFICATION

**PROGAST** is a brown, clear to slightly cloudy liquid supplied in brown glass bottles with a built-in central dropper and a white plastic screw cap.

This is a plant-based material and may be prone to precipitation.

### PRESENTATION

**PROGAST** is available in packs of 20 ml, 50 ml and 100 ml.

### STORAGE INSTRUCTIONS

Store in a dry place, at or 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.

20 ml nappi code: 723067002

50 ml nappi code: 723067001

100 ml nappi code: 723067003

### DATE OF PUBLICATION OF THE PACKAGE INSERT

July 2019

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

CPM04686 01/2020

## PATIENT INFORMATION LEAFLET

### PROGAST

Complementary Medicine. Western Herbal.

### SCHEDULING STATUS

S0

### PROPRIETARY NAME & DOSAGE FORM

**PROGAST** (Oral liquid)

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

**PROGAST** is available without a doctor's prescription. Nevertheless, you still need to use **PROGAST** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **PROGAST** 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 CONTAINS

Each 20 drops (1 ml) contains:

<i>Ulmus rubra</i> Muh. (Slippery elm bark)	75,0 mg
<i>Zingiber officinale</i> L. (Ginger root)	70,0 mg
<i>Matricaria chamomilla</i> L. (German chamomile flower)	66,7 mg
<i>Angelica archangelica</i> L. (Angelica root)	33,3 mg
<i>Carum carvi</i> L. (Caraway fruit)	33,3 mg
<i>Silybum marianum</i> (L.) Gaertn. (Milk thistle fruit)	33,3 mg
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<i>Cynara scolymus</i> L. (Artichoke leaf)	33,3 mg
<i>Glycerhiza glabra</i> L. (Licorice root)	33,3 mg
<i>Mentha piperita</i> L. (Peppermint leaf)	16,7 mg

Contains alcohol 31 % v/v

### WHAT PROGAST IS USED FOR

**PROGAST**'s 10 active ingredients have traditionally been used to reduce symptoms related to gastric and abdominal discomfort like:

- Abdominal Pain & Cramps
- Heartburn
- Bloating & Flatulence
- Chronic Constipation
- Nausea
- Irritable Bowel Syndrome (IBS)

### BEFORE YOU TAKE PROGAST

- Do not take **PROGAST** if you are hypersensitive (allergic to any of the ingredients) or to the *Asteraceae* or *Compositae* families.
- If you have a pre-existing liver disease, consult your doctor before use.
- You should take **PROGAST** under medical guidance if you are suffering from a serious chronic disease and/or undergoing medical treatment.
- Always consult your healthcare professional if you are taking any other medicines, including complementary or traditional medicine.

### Taking PROGAST with food and drink:

There are no known side effects to taking **PROGAST** with food and drink. **PROGAST** is best taken before or with meals.

### Pregnancy and breastfeeding:

Do not use **PROGAST** during pregnancy or while you are breastfeeding your baby, as safety and efficacy have not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

### Driving and using machinery:

No studies on the effect on the ability to drive or use machinery have been performed. It is unlikely that **PROGAST** would affect your ability to drive or use machinery.

### HOW TO TAKE PROGAST

**Adults and children over 12 years:**

Take 20 drops (1,0 ml) 3 times a day.

**Children 6 to 12 years:**

Give 15 drops (0,75 ml) 3 times a day.

**Children 3 to 5 years:**

Give 10 drops (0,5 ml) 3 times a day.

**Children 3 months to 3 years:**

Give 8 drops (0,4 ml) 3 times a day.

### Infants under 3 months:

Give 6 drops (0,3 ml) 3 times a day.

*Children and infants under 3 years to use PROGAST under supervision of a medical healthcare professional: not to be used for longer than 7 (seven) consecutive days in infants under 1 (one) year.*

**SHAKE THE BOTTLE BEFORE USE.** Remove the white screw cap, turn the bottle upside down, and hold at an angle of 45° and give a slight shake. Count the number of drops and mix with a small quantity (30-60 ml) of room temperature water. **PROGAST** should be taken before or with meals, three times a day.

#### If you take more PROGAST than you should:

No reports of over dosage have been found in the literature on the active ingredients used in **PROGAST**. In cases of suspected over dosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre. Treatment should be symptomatic and supportive.

#### If you forget to take PROGAST:

Always take **PROGAST** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule (see "HOW TO TAKE PROGAST"). Do not take a double dose to make up for forgotten individual doses.

### POSSIBLE SIDE EFFECTS

**PROGAST** can have side effects. Should your general health worsen or if you experience any untoward effects whilst taking this medicine, please consult your healthcare professional for advice.

#### *Angelica archangelica* L.

Photosensitivity (*frequency unknown*).

#### *Matricaria chamomilla* L.

Hypersensitivity reactions including anaphylaxis (*frequency unknown*).

#### *Silybum marianum* (L.) Gaertn.

Mild gastrointestinal symptoms such as dry mouth, nausea, upset stomach, gastric irritation and diarrhoea may occur; headache; allergic reactions (dermatitis, urticaria, skin rash, pruritus, anaphylaxis, asthma) may occur (*frequency unknown*).

#### *Melissa officinalis* L.

It can cause nausea, vomiting, abdominal pain, dizziness, and wheezing (*frequency unknown*).

#### *Mentha piperita* L.

The gastro-oesophageal reflux may worsen and heartburn may increase (*frequency unknown*).

#### *Zingiber officinale* L.

Minor gastrointestinal complaints, particularly stomach upset, eructation, dyspepsia and nausea have been reported (*frequent*).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### STORING AND DISPOSING OF PROGAST

STORE ALL MEDICINES OUT OF REACH OF CHILDREN. **PROGAST** should be kept at a temperature at or below 25 °C protected from direct sunlight. Return all unused medicines to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems.

### PRESENTATION OF PROGAST

**PROGAST** is available in packs of 20 ml, 50 ml and 100 ml.

### IDENTIFICATION OF PROGAST

**PROGAST** is a brown, clear to slightly cloudy liquid supplied in brown glass bottles with a built-in central dropper and a white plastic screw cap.

This is a plant-based material and may be prone to precipitation.

### REGISTRATION NUMBER

Will be allocated by Council upon registration.

### NAME OF APPLICANT

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**PROGAST** IS MANUFACTURED IN SOUTH AFRICA.

20 ml nappi code: 723067002

50 ml nappi code: 723067001

100 ml nappi code: 723067003

### DATE OF PUBLICATION OF THIS PATIENT LEAFLET

July 2019

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

CPM04686 01/2020

# Progest

## GASTROINTESTINAL SUPPORT

**PROGAST**  
MONDELIKE VLOEISTOF

**SKEDULERINGSSTATUS**  
S0

### SAMESTELLING

Elke 20 druppels (1 ml) bevat:	
<i>Ulmus rubra</i> Muh. (Rooi-elmbas)	75,0 mg
<i>Zingiber officinale</i> L. (Gemmerwortel)	70,0 mg
<i>Matricaria chamomilla</i> L. (Duitse kamilleblom)	66,7 mg
<i>Angelica archangelica</i> L. (Engelwortel)	33,3 mg
<i>Carum carvi</i> L. (Karwy vrug)	33,3 mg
<i>Silybum marianum</i> (L.) Gaertn. (Melkdistel vrug)	33,3 mg
<i>Melissa officinalis</i> L. (Sitroenbalsemblaar)	33,3 mg
<i>Cynara scolymus</i> L. (Artisjokblaar)	33,3 mg
<i>Glycyrrhiza glabra</i> L. (Soethoutwortel)	33,3 mg
<i>Mentha piperita</i> L. (Peperment blaar)	16,7 mg

Bevat alkohol 31 % v/v

### KATEGORIE EN KLAS

Kategorie D.11.1 Spysverteringstelsel  
Komplementêre Medisyne. Westerse Kruie.

### FARMAKOLOGIESE WERKING

#### Farmakodinamiese eienskappe:

Die 10 kruie-ekstrakte in **PROGAST** word tradisioneel gebruik vir die verligting van simptome in abdominale en gastriese ongemak.

#### Farmakokinetiese eienskappe:

Die aktiewe bestanddele in die formulering is wel bekend. Daar is tans geen Farmakokinetiese studies gedoen op **PROGAST** nie.

### INDIKASIES

Om simptome te verlig wat verband hou met abdominale- en gastriese ongemak soos:

- Buikpyn & Krampe
- Sooi-brand
- Opgeblaseheid & Winderigheid
- Chroniese hardlywigheid
- Naarheid
- Prikkelbare Dersinsdroom (IBS)

### KONTRA-INDIKASIES

Hipersensitiwiteit teenoor enige van die bestanddele, of allergies is vir die plante van die *Asteraceae* of *Compositae* families.

### WAARSKUWINGS EN SPESIALE VOORSORGMATREELS

Pasiënte met voorafbestaande lewersiekte moet hulle dokter raadpleeg alvorens hulle behandeling met **PROGAST** begin.

#### Bestuur en die gebruik van masjinerie:

Geen navorsingstudies is uitgevoer oor die effek op die vermoë om te bestuur of masjinerie te hanteer nie. Dit is onwaarskynlik dat **PROGAST** die vermoë om te bestuur of masjinerie te gebruik sal beïnvloed. Wees egter versigtig tot u seker is u vermoë om hierdie aktiwiteite uit te voer word nie beïnvloed nie.

### INTERAKSIES

Daar is geen interaksies met ander geneesmiddels bekend nie. Pasiënte wat aan ernstige chroniese siektes ly en/of mediese behandeling ondergaan moet **PROGAST** slegs onder mediese toesig en leiding gebruik. **PROGAST** kan deur diabetese gebruik word.

### SWANGERSKAP EN LAKTASIE

Die gebruik van **PROGAST** tydens swangerskap en laktasie is nog nie volledig bestudeer nie en dit behoort slegs onder die leiding van 'n gesondheidsorgspesialis gebruik te word in hierdie omstandighede.

### DOSIS EN GEBRUIKSAANWYSINGS

#### Volwassenes en kinders bo 12 jaar:

Neem 20 druppels (1,0 ml) 3 keer per dag.

#### Kinders 6 tot 12 jaar oud:

Gee 15 druppels (0,75 ml) 3 keer per dag.

#### Kinders 3 tot 5 jaar oud:

Gee 10 druppels (0,5 ml) 3 keer per dag.

#### Kinders 3 maande tot 3 jaar oud:

Gee 8 druppels (0,4 ml) 3 keer per dag.

#### Babas onder 3 maande:

Gee 6 druppels (0,3 ml) 3 keer per dag.

*Kinders en babas onder 3 jaar moet PROGAST onder 'n geneesheer se toesig gebruik en babas onder 1 (een) jaar moet PROGAST nie langer as 7 (sewe) agtereenvolgende dae gebruik nie.*

**SKUD DIE BOTTLE GOED VOOR GEBRUIK.** Verwyder die wit skroef dop, draai die bottel onderstebo, hou teen 'n hoek van 45° en gee 'n ligte skud. Tel die aantal druppels en meng met 'n klein bietjie (30-60 ml) kamertemperatuur water. **PROGAST** moet voor of saam met maaltye geneem word, 3 keer per dag.

### NEWE EFFEKTE

#### *Angelica archangelica* L.

Fotosensitiwiteit (*frekwensie onbekend*).

#### *Matricaria chamomilla* L.

Hipersensitiwiteitsreaksies insluitende anafylakse (*frekwensie onbekend*).

#### *Silybum marianum* (L.) Gaertn.

Ligte gastro-intestinale simptome soos droë mond, naarheid, gastriese irritasie en diarree kan voorkom; hoofpyn; allergiese reaksies (dermatitis, urtikaria, veluitslag, pruritus, anafylakse, asma) kan voorkom (*frekwensie onbekend*).

#### *Melissa officinalis* L.

Dit kan lei tot naarheid, braking, buikpyn, duiseligheid en fluit asemhaling (*frekwensie onbekend*).

#### *Mentha piperita* L.

Die gastro-oesofageale reflux kan vererger en sooi-brand mag toeneem (*frekwensie onbekend*).

#### *Zingiber officinale* L.

Geringe gastro-intestinale ongemak, veral omgekepte maag, toenemende winde breek, dispepsie en naarheid is gerapporteer (*algemeen*).

### BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Daar is geen verslae oor oordosering met die gebruik van die 10 aktiewe bestanddele in **PROGAST** in die literatuur gevind nie. In gevalle van vermoedlike oordosering moet behandeling simptomaties en ondersteunend wees.

### IDENTIFIKASIE

**PROGAST** is 'n bruin helder tot effens troebel vloeistof wat in bruin glasbottels met 'n ingeboude sentrale drupper en 'n wit plastiek skroef dop verskaf word.

Hierdie is 'n plant gebaseerde materiaal en is geneig om 'n neerslag te vorm.

### AANBIEDING

**PROGAST** is beskikbaar in verpakking van 20 ml, 50 ml en 100 ml.

### BERGINGSAAANWYSINGS

Berg op 'n droë plek, teen of benede 25 °C. Beskerm teen direkte sonlig. HOU BUITE BEREIK VAN KINDERS.

### REGISTRASIE NOMMER

Sal toegeteken word deur die Raad tydens registrasie.

### NAAM VAN DIE APLIKANT

Tara Pharmaceuticals (Edms) Bpk  
BEMARK EN VERSPEI DEUR TARA PHARMACEUTICALS (Edms) Bpk  
Unit 9, Fish Eagle Park, Somerset West, Suid-Afrika.  
CO. REG. NO. 1996/011192/07  
TEL: 0861118272

### PROGAST WORD VERVAARDIG IN SUID-AFRIKA.

20 ml nappi code: 723067002

50 ml nappi code: 723067001

100 ml nappi code: 723067003

### DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

Julie 2019

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

CPM04686 01/2020

**SKUD DIE BOTTLE VOOR GEBRUIK.** Verwyder die wit skroef dop, draai die bottel onderstebo, hou teen 'n hoek van 45° en gee 'n ligte skud. Tel die aantal druppels en meng met 'n klein bietjie (30-60 ml) kamertemperatuur water. **PROGAST** moet voor of saam met maaltye geneem word, 3 keer per dag.

### Indien u meer PROGAST geneem het as wat u moes:

Geen inligting is bekend met oordosering van **PROGAST** nie. In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

### Indien u vergeet om PROGAST te neem:

Neem **PROGAST** altyd soos voorgeskryf. Indien u 'n dosis vergeet het, neem dit sou gou as wat u onthou. Indien u egter nie van die vergeete dosis onthou voordat dit tyd is vir die volgende dosis nie, slaan die vergeete dosis oor en keer terug na u gewone doseringskedule (sien "HOE OM PROGAST TE GEBRUIK"). Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosis nie.

### MOONTLIKE NEWE-EFFEKTE

**PROGAST** kan nuwe effekte hê. Indien u algemene gesondheid agteruitgaan terwyl u **PROGAST** gebruik, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

#### *Angelica archangelica* L.

Fotosensitiwiteit (*frekwensie onbekend*).

#### *Matricaria chamomilla* L.

Hipersensitiwiteitsreaksies insluitende anafylakse (*frekwensie onbekend*).

#### *Silybum marianum* (L.) Gaertn.

Ligte gastro-intestinale simptome soos droë mond, naarheid, gastriese irritasie en diarree kan voorkom; hoofpyn; allergiese reaksies (dermatitis, urtikaria, veluitslag, pruritus, anafylakse, asma) kan voorkom (*frekwensie onbekend*).

#### *Melissa officinalis* L.

Dit kan lei tot naarheid, braking, buikpyn, duiseligheid en fluit asemhaling (*frekwensie onbekend*).

#### *Mentha piperita* L.

Die gastro-oesofageale reflux kan vererger en sooi-brand mag toeneem (*frekwensie onbekend*).

#### *Zingiber officinale* L.

Geringe gastro-intestinale ongemak, veral omgekepte maag, toenemende winde breek, dispepsie en naarheid is gerapporteer (*algemeen*).

Indien u enige nuwe-effekte opmerk wat nie in hierdie voubiljet genoem is nie, stel asseblief dadelik u dokter of apteker in kennis.

### BERGING EN WEGDOENING VAN PROGAST

STOOR ALLE MEDIJSYNE BUITE BEREIK EN SIG VAN KINDERS. Bewaar in 'n koel, droë plek by of benede 25 °C. Beskerm teen lig. Moenie gebruik na die vervaldatum op die etiket nie. Neem alle ongebruikte **PROGAST** na u apteker terug. Moenie ongebruikte **PROGAST** in afvoerpype of rioolsisteme, byvoorbeeld toilette weggooi nie.

### AANBIEDING VAN PROGAST

**PROGAST** is beskikbaar in verpakking van 20 ml, 50 ml en 100 ml.

### IDENTIFIKASIE VAN PROGAST

**PROGAST** is 'n bruin, helder tot effens troebel vloeistof wat in bruin glasbottels met 'n ingeboude sentrale drupper en 'n wit plastiek skroef dop verskaf word. Hierdie is 'n plant gebaseerde materiaal en is geneig om 'n neerslag te vorm.

### REGISTRASIE NOMMER:

Sal toegeteken word deur die Raad tydens registrasie.

### NAAM EN BESIGHEIDSDRES VAN DIE HOUER VAN DIE

#### REGISTRASIESERTIFIKAAT

Tara Pharmaceuticals (Edms) Bpk  
BEMARK EN VERSPEI DEUR TARA PHARMACEUTICALS (Edms) Bpk  
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20 ml nappi code: 723067002

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100 ml nappi code: 723067003

### DATUM VAN PUBLIKASIE VAN DIE PASIENT INLIGTINGSBLAD

Julie 2019

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir kwaliteit, veiligheid en beoogde gebruik nie.

CPM04686 01/2020  
Pro-Print