

PROFESSIONAL INFORMATION
PROBILIFT L (drops)

agera™



SCHEDULING STATUS: **50**

PROPRIETARY NAME AND DOSAGE FORM:
PROBILIFT L (drops)

COMPOSITION:

Active substances per 1 ml:
1 billion live bacteria, consisting of a blend of:
Ridulobacterium lactis Bl47®* 200 million CFU
Ridulobacterium longum Bl47®* 150 million CFU
Lactobacillus acidophilus La4®* 200 million CFU
Lactobacillus rhamnosus Lr1®* 150 million CFU
Lactobacillus salivarius Ls1®* 150 million CFU
Lactobacillus acidophilus La5®* 150 million CFU

Tolerase® L (lactase) 1 580 ALU**/ml

*CFU = Colony Forming Units

** Acid Lactase Unit

Tolerase® L is a trademark of DSM.

Inactive ingredients:

Medium Chain Triglyceride (MCT) oil and silicon dioxide.

Preservatives, sugar, flavouring and colourant free.

CATEGORY AND CLASS:

D 34 12 Multiple Substance Formulation

Complementary Medicines: Health Supplement.

PHARMACOLOGICAL ACTION:

Probiotics are beneficial bacteria essential for improving intestinal health. **PROBILIFT L** is a probiotic supplement specifically formulated with 6 probiotic strains and lactase. Probiotics can increase the levels of beneficial bacteria in the gut, creating an environment that is unfavourable to the growth of bad bacteria. When taken on a regular basis, the beneficial bacteria populations are increased in **PROBILIFT L**. In the intestinal tract, the beneficial gut flora populations are increased and therefore, even undigested pathogenic or bad bacteria, are not able to colonise the intestine.

PROBILIFT L contains the enzyme lactase, a naturally occurring enzyme that helps the body to break down the complex sugar lactose, found in milk, breastmilk, some infant formulas and dairy products. Lactase is a different digestive factor, residing at trapped wind and flatulence, vomiting, diarrhoea, and long periods of restlessness and crying.

PROBILIFT L helps the body to digest lactose and manage symptoms of lactose intolerance.

INDICATIONS:

PROBILIFT L has been specially formulated to assist with the symptoms of lactose intolerance. Probiotics should normalise the microbial balance in the human intestines when ingested on a regular basis thereby supporting the functioning of the digestive tract.

CONTRAINDICATIONS:

PROBILIFT L is contraindicated in persons who are hypersensitive to any of the ingredients.

WARNINGS and SPECIAL PRECAUTIONS:

- If you are taking other medicines on a regular basis, including complementary or traditional medicines, please consult your doctor, pharmacist or other healthcare professional for advice on using it with **PROBILIFT L**.

EFFECTS ON THE ABILITY TO DRIVE AND OPERATE MACHINES:

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

INTERACTIONS:

None known.

HUMAN REPRODUCTION:

Pregnancy and lactation:

If you are pregnant or breastfeeding your baby whilst taking **PROBILIFT L**, please consult your doctor, pharmacist or healthcare professional for advice.

PROBILIFT L can be added to infant feeds and breastmilk to assist with lactose digestion.

DOSAGE AND DIRECTIONS FOR USE:

Babies and children up to 12 months old: Add 1 ml with every feed or meal, as directed by your healthcare professional. Give 1 ml with each feed/breastfeeding. Add to the prepared formula feed. Adults: Add 1 ml to a lactose-containing foodstuff and consume immediately.

Storage:

To dispose, use the pipette provided to withdraw 1 ml from the bottle. The drops may be added to feed, meals or drinks. Alternatively, if it can be given straight into the mouth, or onto a spoon. The drops may be changed the taste of the food or drink that this must be added to (as it will change the taste of the food or drink the taste changes the taste of the drops).

SIDE EFFECTS:

None known.

If any adverse reactions occur, please see your doctor, pharmacist or healthcare professional.

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

There are no known symptoms of overdose.

IDENTIFICATION:

PROBILIFT L contains a cream coloured liquid with white suspended particles.

PRESENTATION:

PROBILIFT L is packed in a 30 ml amber glass bottle containing 30 ml of liquid, with a black plastic tamper evident cap and a graduated glass pipette.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Frosted from humidity and light.

Once opened, the product must be used within 3 months.

Store in the original container.

Keep the container tightly closed.

Do not freeze.

Do not refrigerate.

Do not store in direct sunlight.

KEEP OUT OF SIGHT AND REACH OF CHILDREN.

REGISTRATION NUMBER: To be allocated upon registration.

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

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Agera Health Ltd

66 Boulevard Park

Tunney Mayr Drive

Brackenfell

7530

Capetown

South Africa

info@agerahealth.co.za

www.agerahealth.co.za

DATE OF PUBLICATION OF THE PACKAGE INSERT:

January 2019.

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PATIENT INFORMATION LEAFLET

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority (SAHPRA) for its quality, safety or its intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

Complementary Medicines: Health Supplement.

SCHEDULING STATUS: **50**

PROPRIETARY NAME (and dosage form):

PROBILIFT L (drops)

Read this leaflet carefully because it contains important information for you.

• This medicine is available without prescription. However, you still need to use **PROBILIFT L** as directed to get the best results from it.

• Do not share this medicine with any other person.

• Ask your doctor or pharmacist if you need more information or advice.

1. WHAT THIS PRODUCT CONTAINS:

Each dose of 1 ml contains:

The active ingredients in this product are:
The following are the approximate amounts of a blend of:
Ridulobacterium lactis Bl47®* 200 million CFU

Ridulobacterium longum Bl47®* 150 million CFU

Lactobacillus acidophilus La4®* 200 million CFU

Lactobacillus rhamnosus Lr1®* 150 million CFU

Lactobacillus salivarius Ls1®* 150 million CFU

Lactobacillus acidophilus La5®* 150 million CFU

Tolerase® L (lactase) 1 580 ALU**/ml

**CFU = Colony Forming Units

** ALU = Acid Lactase Unit

Tolerase® L is a trademark of DSM.

The inactive ingredients are:

Medium Chain Triglyceride (MCT) oil and silicon dioxide.

Preservative, sugar, flavouring and colourant free.

2. WHAT IS PROBILIFT L USED FOR?

Probiotics are beneficial bacteria, essential for improving intestinal health. **PROBILIFT L** is a probiotic supplement specifically formulated with 6 probiotic strains and lactase.

Probiotics can increase the levels of beneficial bacteria in the gut, creating an environment that is unfavourable to the growth of bad bacteria. When taken on a regular basis, the beneficial bacteria populations are increased in **PROBILIFT L**.

In the intestinal tract, the beneficial gut flora populations are increased and therefore, even undigested pathogenic or bad bacteria, are not able to colonise the intestine.

PROBILIFT L is being used by healthcare practitioners to assist with the symptoms of lactose intolerance, by helping the body to digest lactose. Some individuals may have different symptoms when residing at trapped wind and flatulence, vomiting, diarrhoea, and long periods of restlessness and crying.

PROBILIFT L is being used by healthcare practitioners to assist with the symptoms of lactose intolerance, by helping the body to digest lactose. Some individuals may have different symptoms when residing at trapped wind and flatulence, vomiting, diarrhoea, and long periods of restlessness and crying.

3. BEFORE YOU USE PROBILIFT L:

• Do not use **PROBILIFT L** if you are hypersensitive (allergic) to one of the listed ingredients.

• You are taking other medicines on a regular basis, including complementary or traditional medicines.

PROBILIFT L can be added to baby foods or milks to aid with the digestion of lactose.

Driving and using machinery:

No studies on the effect of **PROBILIFT L** on driving or using machinery have been performed. It is not known whether **PROBILIFT L** would affect your ability to drive or use machinery.

4. HOW TO USE PROBILIFT L:

For oral use only.

Do not exceed the recommended dose.

Take the bottle with before each use.

The usual dose is
Babies and children up to 12 years old: Use 1 ml with every feed or meal, or as directed by
your healthcare professional. Give 1 ml just before breastfeeding. Add 1 ml to the prepared
formula feed.
Adults: Add 1 ml to a hot/cold/boiling foodstuff and consume immediately.
One dose is equivalent to 1 ml.

- use piping nozzle to administer 1 ml from the bottle;
- use a spoon if you are able to feed mouth or drink;
- alternatively, the drops can be given straight into the mouth, or onto a spoon.

The drops will change the taste of the food or drink but must not be added to hot or cold liquids as this will reduce the live cultures of yogurt.

If you use more PROBLIFT L than you should:
There are no known side effects if you take more PROBLIFT L than you should.

In case of over dosage, consult your doctor or pharmacist. If neither is available, contact your nearest poison control center.

If you forget to take PROBLIFT L:
Always take PROBLIFT L 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 take the next dose at the regular time. Do not take double doses. Do not take a double dose to make up for forgotten individual doses.

If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

5. POSSIBLE NIE-EFFECTE:

Not all side effects reported for PROBLIFT L are included in this leaflet. Should you experience any unknown effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for further advice.

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

6. STORING AND DISPOSING OF PROBLIFT L:

- Store at or below 25 °C.
- Keep out of reach of children.
- The expiry date on the product should be used within 3 months.
- Store away from light.
- Store in the original package.
- Store in the original container.
- Keep the container tightly closed.
- Do not use after the expiry date indicated on the label.
- Return all unused medicine or remedies to your pharmacist.
- Do not dispose of unused medicine or remedies in drains or sewerage systems (e.g. KITCHEN SINK).

KEEP OUT OF SIGHT AND REACH OF CHILDREN.

7. PRESENTATION OF PROBLIFT L:

PROBLIFT L is supplied in a clear plastic glass bottle containing 30 ml of liquid, with a black plastic tamper evident cap and graduated glass pipette.

8. IDENTIFICATION OF PROBLIFT L:

PROBLIFT L contains a cream coloured liquid with white suspended particles.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

To be allocated

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Agera Health Pty Ltd
6A Boulevard Park
Tunney Meyer Drive
7530
Pretoria
South Africa
www.agerahealth.co.za

agera™

11. DATE OF PUBLICATION:

January 2019

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PASIËNTINLIGTINGSBLAD

Hierdie ontregelingsblad is vir u deur die SAHPRA gevalhou vir die gehalte, werkings en veiligheid van die bevoegde produk daarvan.

Konfidentialiteit: Mokayor Geselschaftsverwaltung

SKEDULERINGSSTATUS: **[S0]**

EINDOMSNAAM (en dosisverloop):

PROBLIFT L (druppels).

- Lees hierdie behoubarel soukerleukouranggaan dit belangrike infilting vir u bevat.
• Hierdie bevoegde produk is vir u deur die SAHPRA goedgekeur en word PROBLIFT L moet gebruik sou sougaan op die beste manier te sen.
• Hierdie voorlewing! Daar mag nie gebruik word nie.
• Hierdie voorlewing! Daar mag nie gebruik word nie.
• Via u dokter of apoteker in meer uitligting van advise beroekig.

1. WAAT PROBLIFT L BEVAT:

Die aktiewe bestanddele in hierdie produk is:
- *Bifidobacterium faecis* Bl25®^a 200 miljons KVE
- *Bifidobacterium longum* Bl42®^a 200 miljons KVE
- *Lactobacillus rhamnosus* Bl12^a 200 miljons KVE
- *Lactobacillus acidophilus* Bl32^a 150 miljons KVE
- *Lactobacillus paracasei* Bl35^a 150 miljons KVE
- *Lactobacillus salivarius* Bl35^a 150 miljons KVE

Tolerantie*: (laktose) 1 500 SLE**ml

*KVE = Kultuur-vomende Enthoule

**SLE = Suur Laktoos-eenheid

Toleraansigt: Tolerantie van DSM.

Die aktiewe bestanddele is:

Olie van makromettinghuisvark (MK7) en silykloolksied.

Bewaarndeel: suiker, gomsoevier en klousky.

2. WAARVOOR WORD PROBLIFT L GEBRUIK:

Problekt is wenselijk indien, noodsaaklik vir die verleiding van intestinale stoorse en laksus problemte en om instellings van *Bifidobacterium faecis* Bl25^a te bevorder. Problekt kan die vlakke van voedelbare bakteries in die darmkanaal verhoog, en skep 'n ongevoelige wat oengesond was van grondbakteries in die darmkanaal. Hierdie voorlewing! word gevra om die PROBLIFT L in die darmkanaal vry te stel, word die populasie van voedelbare bakteries verhoog en die darmkanaal versoedel. Problift kan die verspreiding van slepe bakteries, kan nie luktus in die darmkanaal vorm nie.

PROBLIFT L bevat die essensiaal laktose, 'n natuurlike voedingsroos wat ons liggaam help om die konsumptie van suiker laktose, wat in melk en ander voedinge aanwezig is, te vermindert. Laktose word in die darmkanaal verter, wat tot vasepragte vind soos windligtheid, loeking, diarree en lang periodes van constans.

PROBLIFT L is spesial gekonfideel om te help met die amptlike van laksos-infirmite, d.w.s. die liggaam se help om laktose te verter. Problekt behoort die mikrobiële balans in die menslike ingewande verhoog of normaliseer wanneer dit gereeld gebruik word. Hierdie voorlewing! word gevra om die amptlike van die appertentiekanaal verhoog.

3. VOOR U PROBLIFT L NEEM:

Moenie PROBLIFT L neem nie:

- Indien u hyperaktiviteit is vir eenige van die bestanddele nie.
- PROBLIFT L is niet kos en drinkevriendelik.

Swangerskap en borstvoeding:

As u swanger is of u baie borrelt nou, of PROBLIFT L gebruik, moet u assief vir vir die bevoegde en gesondheidspakalyk om advous vir.

PROBLIFT L kan by formulering en bewerk gegee word om te help met verting van laktose.

Bestuur en die gebruik van mastrypte:

Grenswaardes is uitgevaardig oor die effek op die verting om te bestuur van mastrypte. Geen verwagtingstaak nie van die verting van die bevoegde en gesondheidspakalyk om advous vir.

4. HOE OM PROBLIFT L TE NEEMME:

Vir elke gebruik moet 1 ml gebruik word. Gebruik nie meer as een en drie maal per dag nie.

PROBLIFT L moet altyd gesien gebruik word soos per dosisinstansies aangedui, Moenie die suugbol doodsonder nie.

Sla die hotel steeglik ekke voor gebruik.

Die gedoseerde is:

Gebruik die gegeue papier om 1 ml uit die bottel te vertrek.

• Die druppels mag nie voeding, malte of vleesfostet gevoeg word.

• Die druppels sal nie smak van die los van dié vleis vereën nie, maar moet nie by want of egtergraplike los of drink gevoeg word nie, aangesien die fytse van losse vleis veroorskade kan word.

Indien u meer PROBLIFT L geneem het as wat u moet:

Grensligting is bekend met oordeling van PROBLIFT L, indien u dus vergert het, neem dit dan u gesondheidspakalyk aangevolg. Gebruik 1 ml net voor hoersvoeding. Voeg 1 ml by die vleesfostet toe.

Wisselvoedsel: Voeg 1 ml by laktose-hanteerende vodsel en granklik oemmidlik.

En dan is geryk aan 1 ml.

Aangesien:

• Gebruik die gegeue papier om 1 ml uit die bottel te vertrek.

• Die druppels mag nie voeding, malte of vleesfostet gevoeg word.

• Die druppels sal nie smak van die los van dié vleis vereën nie, maar moet nie by want of egtergraplike los of drink gevoeg word nie, aangesien die fytse van losse vleis veroorskade kan word.

Indien u enige vry het of onsker is ongeveer iets, raadpleg asseblief u dokter, apoteker of gesondheidspakalyk.

5. MOONTLIKKE NIE-EFFECTE:

Dane geen nie-effecte aangevolg vir PROBLIFT L nie.

Nie alle nie-effecte aangevolg vir PROBLIFT L is aangevolg in hierdie voorlewing! nie.

Die volgende nie-effecte is bekend met oordeling van PROBLIFT L, indien u dus vergert het, neem dit dan u gesondheidspakalyk aangevolg.

Lig asseblief u dokter of apoteker indien u enige nie-effecte onspierk wat nie in hierdie indeling genoem word nie.

6. STORING EN BESKIKKING VAN PROBLIFT L:

Stock my eerste:

• Nadat dit oopgesmack is, moet die bottel binne 3 maande gebruik word.

• Stoor in 'n droog plek.

• Vir die oemmidlik hanteer.

• Houd hierdie gegeue papier om 1 ml uit die bottel te vertrek.

• Moenie gebruik nie die verpakkingstuk op die etiket nie.

Moenie ongebruikte medyjine of middels wegstaan in dinne of moddelstelsels nie.

HOU BIJU SKILLIE BERKIJ VAN KINDERS:

7. AANHOLDING VAN PROBLIFT L:

PROBLIFT L is verkry in 'n 30 ml amber glasbottel wat 30 ml vleesfostet bevat, met 'n plasklouplaat.

8. IDENTIFIKASIE VAN PROBLIFT L:

PROBLIFT L heet in voorlewing! vloslaster met wit gesasperende deeljes.

9. REGISTRASIONNUMMER/VERWYNGNSGNUMMER:

Sal toegelaan word.

10. NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE PROBLIFT L:

RECHTERHEIDSPAKALYK:

Agera Health Pty Ltd

6A Boulevard Park

Tunney Meyer Drive

7530

Pretoria

South Africa

www.agerahealth.co.za

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