

PROFESSIONAL INFORMATION
PROBILIFT D (drops)

agera™

SCHEDULING STATUS: **50**

PROPRIETARY NAME AND DOSAGE FORM:
PROBILIFT D (drops)

COMPOSITION:

Active substances per 1 ml:
1 billion colony forming units consisting of a blend of:
Bifidobacterium lactis Bl-2™* 200 million CFU
Bifidobacterium longum Bl-2™* 150 million CFU
Lactobacillus acidophilus La-1™* 200 million CFU
Lactobacillus rhamnosus Lr-1™* 150 million CFU
Lactobacillus casei Lc-2™* 150 million CFU
Lactobacillus salivarius Ls-3™* 150 million CFU
Vitamin D3 (as cholecalciferol) 400 IU

*CFU = Colony Forming Unit

Inactive Ingredients: Medium Chain Triglyceride (MCT) oil and silicon dioxide.

Preservative: sugar, flavouring and colourant free.

CATEGORY AND CLASS:

D 5412 M Multiple Substance Formulation

Complementary Medicine; Health Supplement.

PHARMACOLOGICAL ACTION:

Probiotics are beneficial bacteria, essential for improving intestinal health. Babies are born without any microflora and are more susceptible to opportunistic gut conditions. **PROBILIFT D** is specially formulated specifically to support the growth of beneficial bacteria, creating an environment where it is difficult for harmful bacteria to grow. By introducing live probiotic cultures to the intestinal tract, the beneficial gut flora populations are increased and transient flora, including pathogenic or bad bacteria, are not able to colonise the intestines. The addition of vitamin D may help with the development of healthy bones and teeth and may contribute to the normal function of the immune system.

Pharmacokinetic properties:

The active ingredients in this formulation are well known. Pharmacokinetic studies have not been performed on **PROBILIFT D**.

INDICATIONS:

PROBILIFT D has been specially formulated for babies. When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract.

CONTRAINDICATIONS:

PROBILIFT D 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, consult your doctor, pharmacist or other healthcare professional for advice on safety if you are pregnant or breastfeeding.
- Vitamin D should be used with caution in patients with hypercalcaemia.
- Increased sensitivity to vitamin D is observed in patients with renal impairment and having a history of kidney disease.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINERY:

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

INTERACTIONS:

The effects of vitamin D may be reduced in patients taking barbiturates or *met*-conjugants due to effects on metabolism of vitamin D.

HUMAN AND ANIMAL TOXICOLOGY:

Pregnancy and lactation:

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

DOSAGE AND DIRECTIONS FOR USE:

For babies aged 0-12 months: Take 1 ml orally daily, or as directed by your healthcare professional. One dose is equivalent to 1 ml. If your baby is on antibiotics, increase the dose to 1 ml three times per day for the duration of the antibiotic course.

Shake the bottle well before use.

To dispense, use pipette provided to withdraw 1 ml from the bottle. The drops may be given straight into the mouth, or onto a spoon. The drops will not change the taste of the food or drink. Do not add to hot or warm food or drink as the heat damages the live culture of bacteria.

For adults and children older than 3 years who wish to take the drops: Take 1 ml orally daily, as directed by your healthcare professional.

SIDE EFFECTS:

None known.

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

KNOWN SYMPTOMS OF OVERDOSEAGE AND PARTICULARS OF ITS TREATMENT:

There are no known symptoms of overexposure.

If symptoms of overdose arise, discontinue use of the medicine. Treatment is symptomatic and supportive.

IDENTIFICATION:

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

PRESENTATION:

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

STORAGE INSTRUCTIONS:

Store at or below 25°C.
Protect from light and heat.
Once opened, the bottle should be used within 3 months.
Store in a dry, original container.
Keep the container tightly closed.
Do not use after the expiry date stated on the label.

KEEP OUT OF REACH OF CHILDREN:

REGISTRATION NUMBER: To be allocated upon registration.

This registered 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 Solutions Ltd
64 Boulevard Park
Tinten Meyer Drive
Bellville 7535
Cape Town,
South Africa
info@agerahealth.co.za
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DATE OF PUBLICATION OF THE PACKAGE INSERT:

January 2019 FDD369102018v1

PATIENT INFORMATION LEAFLET

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

Complementary Medicine; Health Supplement.

SCHEDULING STATUS: **50**

PROPRIETARY NAME (and dosage form):

PROBILIFT D (drops)

Read the leaflet carefully, because it contains important information for you.

- This medicine is available, without prescription. However, you still need to use **PROBILIFT D** as directed to get the best results from it.
- Do not share this medicine with any other person.
- Do not give this medicine to anyone else.
- You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 2 days.

1. WHAT IS PROBILIFT D?

The active ingredients in this product are:

1 billion colony forming units consisting of a blend of:
Bifidobacterium lactis Bl-2™* 200 million CFU
Bifidobacterium longum Bl-2™* 150 million CFU
Lactobacillus acidophilus La-1™* 200 million CFU
Lactobacillus rhamnosus Lr-1™* 150 million CFU
Lactobacillus casei Lc-2™* 150 million CFU
Lactobacillus salivarius Ls-3™* 150 million CFU
Vitamin D3 (as cholecalciferol) 400 IU

The inactive ingredients are: Medium Chain Triglyceride (MCT) oil and silicon dioxide.

Preservative: sugar, flavouring and colourant free.

2. WHAT IS PROBILIFT D USED FOR?

Probiotics are beneficial bacteria, essential for improving intestinal health. Babies are born without any microflora and are more susceptible to opportunistic gut conditions. **PROBILIFT D** is specially formulated specifically to support the growth of beneficial bacteria, creating an environment where it is difficult for harmful bacteria to grow. By introducing live probiotic cultures to the intestinal tract, the beneficial gut flora populations are increased and transient flora, including pathogenic or bad bacteria, are not able to colonise the intestines. The addition of vitamin D may help with the development of healthy bones and teeth and may contribute to the normal function of the immune system.

3. HOW SHOULD PROBILIFT D BE USED?

Always take PROBILIFT D exactly as per dosage instructions or as directed by your doctor or healthcare professional before taking PROBILIFT D.

• If you are hypersensitive (allergic) to any of the listed ingredients.

Consult your doctor or qualified healthcare practitioner before using this medicine if:

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

Driving and using machinery:

Always tell your healthcare professional if you are taking other medicines on a regular basis.

Using other medicines with PROBILIFT D:

Always tell your healthcare professional if you are taking other medicines on a regular basis.

• The effects of vitamin D may be reduced/weakened if taken with barbiturates or anti-

4. HOW TO USE PROBILIFT D:

For oral use only.

Always take **PROBILIFT D** exactly as per dosage instructions or as directed by your

doctor or healthcare professional before taking **PROBILIFT D**.

• Do not exceed the recommended dose.

Shake the bottle well before each use.

The usual dose is:
For children younger than 3 years of age: Give 1 ml daily, or as directed by your healthcare provider.
For children over 3 years of age: Give 1 ml twice a day.
If your baby is on antibiotics, increase the dose to 1 ml three times per day for the duration of the antibiotic course, and for 3 days after.

To dispense:
• The dropper provided to withdraw 1 ml from the bottle.
• The drops may be given straight into the mouth, or onto a spoon.
• The drops will not change the taste of the food or drink but must not be added to hot or cold liquids as this may damage the live cultures of bacteria.

For adults and children older than 2 years who wish to take the drops: Take 1 ml daily, or as directed by your healthcare professional.

If you are more PROBLIFT D than you should:
There are no known side effects if you take more PROBLIFT D than you should. If you feel the effects of overuse, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forgot to take PROBLIFT D:
Always take PROBLIFT D as prescribed. If you miss a dose, take it as soon as you remember. If you have taken the missed dose later than the time for the next dose, skip the missed dose and go back to your regular dosing schedule (see "HOW TO TAKE PROBLIFT D"). Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE-EFFECTS:

There are no known side effects of PROBLIFT D.
Not all side effects reported for PROBLIFT D are included in this leaflet. Should you experience any adverse effects whilst taking the medicine please consult your doctor, pharmacist or other healthcare professional for advice.

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

6. STORAGE AND DISPOSAL OF PROBLIFT D:

- Store at or below 25 °C.
- Once opened, the bottle should be used within 3 months.
- Store in a cool place.
- Store in the original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the label.
- Do not store in direct sunlight or near heat sources.
- Do not dispose of unused medicine or remedies in drains or sewerage systems (e.g. toilets).

7. KIDNEY OF SIGHT AND REACH OF CHILDREN:

7. PRESENTATION OF PROBLIFT D:
PROBLIFT D is packed in a 30 ml amber glass bottle with a black plastic tamper evident cap and graduated glass pipette.

8. IDENTIFICATION OF PROBLIFT D:

PROBLIFT D contains a cream coloured liquid with white suspended particles

9. REGISTRATION NUMBER/REFERENCE NUMBER:

10. NAME AND ADDRESS OF REGISTRATION HOLDER:
Agera Health (Pty) Ltd
6A Boulevard Park
101 Meyer Drive
Bridville
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11. DATE OF PUBLICATION:

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PASIËNTINLIGTINGSBLAD

Hierdie oorgangsstelsel-medicament is uitgevaardig deur SAHPRA gevalideer vir die gebruik van volwasse en kinders van 2 tot 12 jaar.

Kompleksiteit Mediese Gevolgeloosheid

SKOUDERLINGSTATUS: **[S9]**

EINDOMSNAAM (en dosisvorm):

PROBLIFT D (droppels).

Lees hierdie hele vondstblad voor aanvoer dit belangrike inligting vir u binne. Hierdie medicament is bestuurbaar onder voorvat, alhoewel u steeds PROBLIFT D moet gebruik soos aangewys deur die bestuurende arts. Houd daarop dat u dit wort moet lees. Maak hierdie medycine niet ongeag nie omdat dit nie goed werk nie. Maak hierdie medycine nie om te verkoop nie omdat dit nie goed werk nie. U moet dit dakter raadpleeg indien u sumpfante vervaag of nie verbeter binne 7 dae nie.

1. DATUM PROBLIFT D BEVAT:

Die aktiewe bestanddele in hierdie produk is:
Bifidobacterium longum Lc-12®¹ 200 miljoen KVE
Bifidobacterium breve Lc-14®¹ 200 miljoen KVE
Lactobacillus rhamnosus (RE) 150 miljoen KVE
Lactobacillus acidophilus Lc-32®¹ 150 miljoen KVE
Lactobacillus salivarius Lc-33®¹ 150 miljoen KVE
Vitamin D3 (as koldikalifer) 400 IU

*KVE=Kolonievormende Enhekk

Die enklaatvoer bestanddele is: Olive oil, medium-chain triglycerides (MCT) en niklendekined.

Braamseidelyk, suiker, gomstevy, smaakstev.

2. WAARVOOR WORD PROBLIFT D GEBRUIK?:
Hierdie medicament word gebruik vir die verbetering van intestinale gesondheid. Indas word sonder enige artifisiale geboor en is nie meer valsaar vir gebruik nie. Hierdie medicament bevat aktiewe bestanddele wat gevulde en proteasse stamine om vitamine D gevormuleer is. Daar is baie so drieët met PROBLIFT D aan u toe kan u sy/u hoor bestuurlike lang in die darmstelsel versirk om die darmwand te ontspan. Dit maak die darmwand minder gevoelig vir die darmwand verloop, en skop 'n ontgaande wat organisa op u die groei van skadelike bakteries te verminder. Hierdie medicament bevat ook aktiewe bestanddele wat die populasies van voordele darmflora verhoog op die congoepathies, waaronder patogene of die bakterie. Dan nu kolonies in die darm kan verminder. Die bewerking van vitamine D3 in hierdie medicament is 'n groote bane en baie in hierdie tyd die normale werking van die immunitate.

PROBLIFT D is spesial vir babies geformuleer. Wanneer gereeld ingeneem word, kan dit die ontwikkeling van die darmstelsel in die menslike ingawande te verbeter en soekende die funksionering van die spoorwegmagstelsel te verbeter. 3. VOOR U PROBLIFT D NEEKELE:

Moenie PROBLIFT D neekele nie van die bestondende ric.

Raakleer en gescreuer of apteker vir gebruik houen:
As u sanger is of u baie bonverdoed houet u PROBLIFT D geleuk, moet u asseblief vir Raakleer en gescreuer of apteker vir gebruik houen.

Lag aflyk is gesondheidspakketten in waarste en inhouke op 'n gerolde grondslag neem, indienkom kompleksiteit of toetsaamle modysie.

PROBLIFT D moet met water dring:

Om die bestanddele hierdie medicament te ontdien moet u die medicament neem en dan met water dring.

Swanger en borserweling:

As u sanger is of u baie bonverdoed houet u PROBLIFT D geleuk, moet u asseblief vir Swanger en borserweling houen.

Gemengvaartes is nadelig vir die effek op die vermoed om te bestuur of magneet te hanter en dat is onregtig dat PROBLIFT D die vermoed om te bestuur met die vermoed om te bestuur of magneet te hanter.

Gebrook van PROBLIFT D na ander medycine:
As u ander medycine op 'n gerolde basis gebruik, indienkom kompleksiteit of tradisionele medycine, raakleer en dakter, apteker of ander gesondheidspakketten om advies.

PROBLIFT D moet nie met ander medycine:
As u ander medycine op 'n gerolde basis gebruik, indienkom kompleksiteit of tradisionele medycine, raakleer en dakter, apteker of ander gesondheidspakketten om advies.

4. HOE OM PROBLIFT D TE NEEMGEDE:

PROBLIFT D moet altyd presies geleuk word soos per doseringinstruksies aangehef, of soos dient u dakter of apteker aangevul.

Skad die hotel deeglik elke keer voor gebruik.

Vir kinders jonger as 2 jaar oud: Gee 1 ml daglik, of soos dient u gesondheidspakketten sanger. As u dooi is, moet u die dooi van die lees of dakt vir ander sanger, maar moet nu by die dooi tot 1 ml die dooi vir die dooi.

Aanbeveling:
• Die dooipipet moet in die dooi op 'n lopig gegee word.

• Die dooipipet sal nie die smak van die lees of dakt verander nie, maar moet nu by die dooi tot 1 ml die dooi vir die dooi.

Vir volwassenes en kinders ouer as 2 jaar wat verkoop om die druppels te druk. Drink 1 ml daglik, of soos dient u gesondheidspakketten sanger.

Inden u meer PROBLIFT D geneem het as u moet:

Norm PROBLIFT D selby soos voldoend. Inden u 'n dooi vergat het, norm dit soos as wat u enhou. Inden u vter van die vorige dooi vergat voordat dit tyd om die dooi te neem, moet u die dooi van die vorige dooi neem en dan die dooi te neem.

5. MOONTLIKJE NUWE-EFFECTE VAN PROBLIFT D:

Die genoemde bestanddele van PROBLIFT D is in hierdie vondstblad nie in hierdie vondstblad nie.

Indien u gesondheidswelke vertrek of ander medycine roksake enoor wat nie met hier gelyk is, moet u 'n dakter, apteker of gesondheidspakketten raadpleeg.

Lag asseblief u dakter of apteker inden u enige nuwe-effekte onspier wat nie in hierde

6. SIEKHEID, REWARDING EN BESKIKKING VAN PROBLIFT D:

PROBLIFT D is verpak in 'n 30 ml amber glashouer met 'n swart plastiek pentevry

7. IDENTIFIKASIE VAN PROBLIFT D:
PROBLIFT D bestuur 'n roetvlokkige vleisot of wit gesuspenderde deeltjies.

9. REGISTRASIONOMMER/VERWYNNINGSNOMMER:

Sal toegelaan word.

10. NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE VLOKKIE:

Agera Health (Pty) Ltd
6A Boulevard Park
101 Meyer Drive
Bridville
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www.agerahealth.co.za

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