

SCHEDULING STATUS: **S0**

**PROBIFLORA ADULT EVERYDAY FLORA BALANCE (2 Strain)**

**1 billion CFU, capsules**

***Lactobacillus rhamnosus* LR-32 and *Bifidobacterium longum* BI-05**

**Contains sugar: Each capsule contains not more than 10 mg  
glucose/fructose/sucrose blend in inulin.**

**Category D: Complementary Medicine**

**Health Supplements: 34.9 Probiotics**

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

**Read all of this leaflet carefully because it contains important information for you**

**Probiflora Adult Everyday Flora Balance (2 Strain)** is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use **Probiflora Adult Everyday Flora Balance (2 Strain)** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Probiflora Adult Everyday Flora Balance (2 Strain)** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

**What is in this leaflet**

1. What **Probiflora Adult Everyday Flora Balance (2 Strain)** is and what it is used for.
2. What you need to know before you take **Probiflora Adult Everyday Flora Balance (2 Strain)**
3. How to take **Probiflora Adult Everyday Flora Balance (2 Strain)**
4. Possible side effects
5. How to store **Probiflora Adult Everyday Flora Balance (2 Strain)**
6. Contents of the pack and other information.

**1. What Probiflora Adult Everyday Flora Balance (2 Strain) is and what it is used for**  
**Probiflora Adult Everyday Flora Balance (2 Strain)** is a probiotic.

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/gut.

**2. What you need to know before you take Probiflora Adult Everyday Flora Balance (2 Strain)**

**Do not take Probiflora Adult Everyday Flora Balance (2 Strain):**

- If you are hypersensitive (allergic) to *Bifidobacterium longum*, *Lactobacillus rhamnosus* or any of the other ingredients of **Probiflora Adult Everyday Flora Balance (2 Strain)** (listed in section 6).

### **Warnings and Precautions**

Take special care with **Probiflora Adult Everyday Flora Balance (2 Strain)**:

- Consult a healthcare provider before taking **Probiflora Adult Everyday Flora Balance (2 Strain)** if you have fever, vomiting, bloody diarrhoea or severe stomach pain.
- Stop taking **Probiflora Adult Everyday Flora Balance (2 Strain)** and consult a healthcare provider if symptoms of upset stomach (e.g. diarrhoea) occur or worsen.

### **Other medicines and Probiflora Adult Everyday Flora Balance (2 Strain)**

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Antibiotic medicines (used to treat bacterial infections) may decrease the effectiveness of **Probiflora Adult Everyday Flora Balance (2 Strain)** if taken at the same time. You should take **Probiflora Adult Everyday Flora Balance (2 Strain)** at least 2 hours before or after antibiotic medicines.

### **Pregnancy, breastfeeding and fertility**

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 healthcare provider for advice before taking **Probiflora Adult Everyday Flora Balance (2 Strain)**.

Safety in fertility, pregnancy and lactation has not been established.

### **Driving and using machines**

It is not always possible to predict to what extent **Probiflora Adult Everyday Flora Balance (2 Strain)** may interfere with your daily activities. Ensure that you do not engage in the above activities until you are aware of the measure to which **Probiflora Adult Everyday Flora Balance (2 Strain)** affects you.

### **Probiflora Adult Everyday Flora Balance (2 Strain) contains fructose, glucose and sucrose**

- Each capsule contains not more than 10 mg blend of fructose/glucose and sucrose. You should take into account the additive effect of products containing fructose (or sorbitol) and dietary intake of fructose (or sorbitol) when taken or used together with **Probiflora Adult Everyday Flora Balance (2 Strain)**.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **Probiflora Adult Everyday Flora Balance (2 Strain)**.

### 3. How to take Probiflora Adult Everyday Flora Balance (2 Strain)

Do not share medicines prescribed for you with any other person.

Always take **Probiflora Adult Everyday Flora Balance (2 Strain)** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: Take 1 capsule daily in the morning.

Dosage can be increased to 2 capsules a day if needed or as directed by your healthcare professional.

Take at least 2 hours before or after antibiotics.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

#### **If you take more Probiflora Adult Everyday Flora Balance (2 Strain) than you should**

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 take Probiflora Adult Everyday Flora Balance (2 Strain)**

Do not take a double dose to make up for forgotten individual doses.

### 4. Possible Side Effects

**Probiflora Adult Everyday Flora Balance (2 Strain)** can have side effects.

Not all side effects reported for **Probiflora Adult Everyday Flora Balance (2 Strain)** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Probiflora Adult Everyday Flora Balance (2 Strain)**, please consult your healthcare provider for advice.

**Probiflora Adult Everyday Flora Balance (2 Strain)** is generally well tolerated.

Tell your doctor if you notice any of the following:

#### Less frequent side effects:

- worsening diarrhoea,
- abdominal (stomach) pain,
- constipation,
- gas.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **Probiflora Adult Everyday Flora Balance (2 Strain)**.

### 5. How to store Probiflora Adult Everyday Flora Balance (2 Strain)

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store away from direct sunlight and moisture.
- Do not use after the expiry date stated on the carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

### 6. Contents of the pack and other information

#### What Probiflora Adult Everyday Flora Balance (2 Strain) contains:

The active substances are:

|                                      |                |
|--------------------------------------|----------------|
| <i>Lactobacillus rhamnosus</i> LR-32 | 1 billion CFU* |
| <i>Bifidobacterium longum</i> BI-05  |                |

\* Colony forming units

The other ingredients are: Hypromellose (HPMC), inulin/oligofructose (containing fructose, glucose and sucrose), magnesium stearate and microcrystalline cellulose.

#### What Probiflora Adult Everyday Flora Balance (2 Strain) looks like and contents of the pack

A white capsule containing cream coloured powder with light yellow granules.

30 capsules in a white HDPE round jar with a white PP screw on flip top lid.

#### Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

Customer Care: 0860 ADCOCK/232625

**This leaflet was last revised in:**

20 June 2024

**Registration number:**

To be allocated

adcock ingram 

T038284 10/2024

SKEDULERINGSSTATUS: S0

**PROBIFLORA ADULT EVERYDAY FLORA BALANCE (2 Strain)**

**1 biljoen KVE, kapsules**

***Lactobacillus rhamnosus* LR-32 en *Bifidobacterium longum* BI-05**

**Bevat suiker: Elke kapsule bevat nie meer as 10 mg  
glukose/fruktose/sukrose-vermenging in inulien nie.**

**Kategorie D: Komplementêre Medisyne**

**Gesondheidsaanvullings: 34.9 Probiotika**

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

**Lees die hele voubiljet noukeurig omdat dit belangrike inligting bevat**

**Probiflora Adult Everyday Flora Balance (2 Strain)** is beskikbaar sonder 'n doktersvoorskrif, om u gesondheid mee te onderhou. Nogtans moet u steeds **Probiflora Adult Everyday Flora Balance (2 Strain)** versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voubiljet. U sal dit dalk weer moet lees.
- Moenie **Probiflora Adult Everyday Flora Balance (2 Strain)** met enigiemand anders deel nie.
- Vra u gesondheidsorgkundige of apteker indien u meer inligting of advies benodig.

**Wat in hierdie voubiljet staan**

1. Wat **Probiflora Adult Everyday Flora Balance (2 Strain)** is en waarvoor dit gebruik word
2. Wat u moet weet voor u **Probiflora Adult Everyday Flora Balance (2 Strain)** neem
3. Hoe om **Probiflora Adult Everyday Flora Balance (2 Strain)** te neem
4. Moontlike newe-effekte
5. Hoe om **Probiflora Adult Everyday Flora Balance (2 Strain)** te neem
6. Inhoud van die verpakking en ander inligting

**1. Wat Probiflora Adult Everyday Flora Balance (2 Strain) is en waarvoor dit gebruik word**  
**Probiflora Adult Everyday Flora Balance (2 Strain)** is 'n probiotikum.

Met gereelde inname behoort probiotika die mikrobiëse balans in die menslike ingewande te verbeter of te normaliseer en daardeur die werking van die spysverteringskanaal/derms verbeter.

**2. Wat u moet weet voor u Probiflora Adult Everyday Flora Balance (2 Strain) neem**  
**Moenie Probiflora Adult Everyday Flora Balance (2 Strain) neem:**

- Indien u hipersensitief (allergies) vir *Bifidobacterium longum*, *Lactobacillus rhamnosus* of enige van die ander bestanddele van **Probiflora Adult Everyday Flora Balance (2 Strain)** is nie (gelys in afdeling 6).

### Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met **Probiflora Adult Everyday Flora Balance (2 Strain)**:

- Raadpleeg 'n gesondheidsorgkundige voor u **Probiflora Adult Everyday Flora Balance (2 Strain)** neem indien u koors, braking, bloederige diarree of erge maagpyn het.
- Staak die gebruik van **Probiflora Adult Everyday Flora Balance (2 Strain)** en raadpleeg 'n gesondheidsorgkundige indien simptome van 'n omgekrapte maag (bv. diarree) voorkom of vererger.

### Ander medisyne en Probiflora Adult Everyday Flora Balance (2 Strain):

Lig altyd u gesondheidsorgkundige in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)

- Antibiotiese medisyne (vir behandeling van bakteriële infeksies) kan die doeltreffendheid van **Probiflora Adult Everyday Flora Balance (2 Strain)** verswak as dit op dieselfde tyd geneem word. U moet **Probiflora Adult Everyday Flora Balance (2 Strain)** minstens 2 uur voor of ná antibiotiese medisynes neem.

### Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of van plan is om 'n baba te kry, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir advies voor u **Probiflora Adult Everyday Flora Balance (2 Strain)** neem.

Veiligheid vir vrugbaarheid, swangerskap en laktasie is nog nie vasgestel nie.

### Bestuur en gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel in watter mate **Probiflora Adult Everyday Flora Balance (2 Strain)** by u alledaagse aktiwiteite kan inmeng nie. Maak seker dat u nie die bogenoemde aktiwiteite verrig tot u weet in watter mate **Probiflora Adult Everyday Flora Balance (2 Strain)** u aantass nie.

### Probiflora Adult Everyday Flora Balance (2 Strain) bevat fruktose, glukose en sukrose

- Elke kapsule bevat nie meer nie as 10 mg van 'n vermenging van fruktose/glukose en sukrose.

U moet die additiewe effek van produkte wat fruktose (of sorbitol) bevat en voedselinname van fruktose (of sorbitol) in ag neem voor dit saam met **Probiflora Adult Everyday Flora Balance (2 Strain)** geneem of gebruik word.

Indien u dokter u ingelig het dat u onverdraagsaamheid teenoor sekere suikers het, kontak u dokter voor u **Probiflora Adult Everyday Flora Balance (2 Strain)** neem.

### 3. Hoe om Probiflora Adult Everyday Flora Balance (2 Strain) te neem

Moenie medisynes wat vir u voorgeskryf is met enigiemand anders deel nie.

Neem **Probiflora Adult Everyday Flora Balance (2 Strain)** altyd presies soos voorgeskryf in hierdie voubiljet of soos u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Die algemene dosis is:

Volwassenes: Neem 1 kapsule daaglik in die oggend.

Dosering kan tot 2 kapsules per dag verhoog word indien nodig, of soos aangedui deur u gesondheidsorgkundige.

Neem minstens 2 uur voor of ná antibiotika.

'n Gebalanseerde dieet is die doeltreffendste en veiligste manier om goeie voedingswaarde, gesondheid, liggaamssamestelling sowel as geestelike en fisiese verrigting te bereik.

### Indien u meer Probiflora Adult Everyday Flora Balance (2 Strain) neem as wat u moet

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van die twee beskikbaar is nie, kontak die naaste hospitaal of gifhulpentrum.

### Indien u vergeet om Probiflora Adult Everyday Flora Balance (2 Strain) te neem

Moenie 'n dubbele dosis neem om die vergete individuele dosisse op te maak nie.

### 4. Moontlike newe-effekte

**Probiflora Adult Everyday Flora Balance (2 Strain)** kan newe-effekte hê.

Nie alle newe-effekte wat vir **Probiflora Adult Everyday Flora Balance (2 Strain)** aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid sou verswak of indien u enige ongewenste effekte ervaar terwyl u **Probiflora Adult Everyday Flora Balance (2 Strain)** neem, raadpleeg asseblief u gesondheidsorgkundige vir advies.

**Probiflora Adult Everyday Flora Balance (2 Strain)** word oor die algemeen goed verdra.

Lig u dokter in indien u enige van die volgende opmerk:

#### Minder algemene newe-effekte:

- verergerende diarree,
- buikpyn (maagpyn),
- hardlywigheid,
- winderigheid.



Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem is nie, lig asseblief u dokter of apteker in.

### Aanmelding van newe-effekte

Indien u newe-effekte ervaar, lig u dokter, apteker of verpleegkundige in. U kan newe-effekte ook regstreeks by SAHPRA aanmeld via die Med Safety App (Medsafety X SAHPRA) en elektronies aanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **Probiflora Adult Everyday Flora Balance (2 Strain)** te verskaf.

### 5. Hoe om Probiflora Adult Everyday Flora Balance (2 Strain) te bêre

Bêre alle medisyne buite bereik van kinders.

- Bêre teen of benede 25 °C.
- Bêre beskut teen direkte sonlig en vog.
- Moenie gebruik ná die vervaldatum wat op die kartonhouer / bottel aangedui is nie.
- Neem alle ongebruikte medisyne na u apteker terug.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

### 6. Inhoud van die verpakking en ander inligting

**Wat Probiflora Adult Everyday Flora Balance (2 Strain) bevat:**

Die aktiewe bestanddele is:

|                                      |                |
|--------------------------------------|----------------|
| <i>Lactobacillus rhamnosus</i> LR-32 | 1 biljoen KVE* |
| <i>Bifidobacterium longum</i> BI-05  |                |

\* Kolonievormende eenhede

Die ander bestanddele is: Hipromellose (HPMC), inulien/oligofruktose (bevat fruktose, glukose en sukrose), magnesiumstearaat en mikrokristallyne sellulose.

### Hoe Probiflora Adult Everyday Flora Balance (2 Strain) lyk en inhoud van die verpakking

'n Wit kapsule wat roomkleurige poeier met liggeel korrels bevat.

30 kapsules in 'n ronde wit HDPE botteltjie met 'n wit PP skroefprop met 'n opwipdeksel.

### Houer van Registrasiesertifikaat

Adcock Ingram Limited

New Road 1,

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Kliëntediens: 0860 ADCOCK/232625

**Hierdie voubiljet is mees onlangs hersien op:**

20 Junie 2024

**Registrasienuommer:**

Moet toegeken word

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T038284 10/2024