

PROFESSIONAL INFORMATION

Releaf Probiotic kids chews



SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

Releaf Probiotic kids chews (chewable tablets).

COMPOSITION:

Each chew tablet contains:

1 billion CFU (colony forming units) HOWARU® Bifido probiotics consisting of a blend:

Bifidobacterium lactis; Bi-07®

Lactobacillus casei; Lc-11®

Lactobacillus acidophilus; La-14®

Inactive ingredients: Citric acid, grape skin extract, isomalt, magnesium stearate and mixed berry flavour.

Sugar free.

Contains sweetener (20 mg CSA 80 (contains acesulfame potassium, sodium saccharin and sodium cyclamate)).

CATEGORY AND CLASS:

Category of medicine: D

Class: D 34.9 Probiotics.

Complementary Medicine: Health Supplement.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Releaf Probiotic kids chews contain a combination of 3 probiotic strains, which assist in improving or normalizing the microbial balance in the human intestines and thereby improving the functioning of the digestive tract/gut.

Bifidobacterium lactis; Bi-07®

Lactobacillus casei; Lc-11®

Lactobacillus acidophilus; La-14®

Pharmacokinetic properties:

The active ingredients in this formulation is well known. Pharmacokinetic studies have not been conducted **Releaf Probiotic kids chews** and other medicines or food.

INDICATIONS:

Releaf Probiotic kids chews contain a combination of 3 probiotic strains, which assist in improving the microbial balance in the human intestines and thereby improving the functioning of the digestive tract.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Not recommended during pregnancy and/or lactation.

WARNINGS and SPECIAL PRECAUTIONS:

Contains isomalt and may have a laxative effect.

Might cause gastrointestinal reactions.

Effects on the ability to drive and use machinery:

No studies on the effect of **Releaf Probiotic kids chews** on the ability to drive or operate machinery were performed. It is unlikely that **Releaf Probiotic kids chews** would affect the ability to drive or operate machinery. Patients should not drive or operate machinery until it is established that their ability to perform such activities has not been affected.

INTERACTIONS:

Adverse effects have not become known with the simultaneous ingestion of **Releaf Probiotic kids chews** with food and drink.

Antibiotics might decrease the effects of probiotics (bifidobacterial and lactobacillus species).

Advise patients to take antibiotics and this product at least 2 hours apart. Avoid taking probiotics (bifidobacterial and lactobacillus species) during digestive tract surgery, as it might contribute to infection.

Lactobacillus could cause infection in patients with short bowel syndrome, who are immunocompromised, or who are taking immunosuppressants such as cyclosporine, tacrolimus, azathioprine and cancer chemotherapeutic agents like cyclophosphamide and cisplatin.

HUMAN REPRODUCTION:

Pregnancy and lactation:

Not recommended for use during pregnancy and lactation.

Consult a healthcare professional for further information.

DOSAGE AND DIRECTIONS FOR USE:

Children ages 3 years and older: Chew 1 chew tablet daily.

It is advisable to stagger the administration of the antibiotic and probiotic such that the probiotic is administered at least two hours after the antibiotic dose, otherwise the antibiotic may reduce the efficacy of the probiotic microorganisms. Probiotics must be administered for at least one week following the completion of the antibiotic course.

If the symptoms worsen or persist, please consult your healthcare practitioner.

SIDE EFFECTS:

Gastrointestinal disorders:

Less frequent: Diarrhoea.

Less frequent: Bloating and flatulence.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No known symptoms of overdose.

Treatment of overdose is symptomatic and supportive.

IDENTIFICATION:

A round pinkish/purple chewable tablet with a mixed berry flavour.

PRESENTATION:

10's: The chew tablets are available in PVC/aluminium blister strip, with each blister strip containing 10 chew tablets. Each carton contains 1 blister strip.

30's: The chew tablets are available in PVC/aluminium blister strip, with each blister strip containing 10 chew tablets. Each carton contains 3 blister strips.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated.

Releaf Probiotic kids chews has not been evaluated by the SAHPRA for its quality, safety or intended use. **Releaf Probiotic kids chews** does not intend to prevent or cure any form of illness or disease, and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Keep away from children. Do not exceed the recommended dose.

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

RELEAF PHARMACEUTICALS (PTY) LTD

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PATIENT INFORMATION LEAFLET

This leaflet tells you about **Releaf Probiotic kids chews**.

Health Supplement

SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

Releaf Probiotic kids chews (chewable tablets).

Read all of this leaflet carefully because it contains important information for you. **Releaf Probiotic kids chews** is available without a doctor's prescription. Nevertheless, you still need to use **Releaf Probiotic kids chews** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Do not share **Releaf Probiotic kids chews** with any other person.

Ask your pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve.

WHAT Releaf Probiotic kids chews CONTAINS:

Each chew tablet contains:

Active ingredients are:

1 billion CFU (colony forming units) HOWARU® Bifido probiotics consisting of a blend:

Bifidobacterium lactis; Bi-07®

Lactobacillus casei; Lc-11®

Lactobacillus acidophilus; La-14®

Inactive ingredients: Citric acid, grape skin extract, isomalt, magnesium stearate and mixed berry flavour.

Contains sweetener (20 mg CSA 80 (contains acesulfame potassium, sodium saccharin and sodium cyclamate)).

Sugar free.

WHAT Releaf Probiotic kids chews IS USED FOR:

Releaf Probiotic kids chews contain a combination of 3 probiotic strains, which assist in improving the microbial balance in the human intestines and thereby improving the functioning of the digestive tract.

BEFORE YOU TAKE Releaf Probiotic kids chews:

Do NOT take Releaf Probiotic kids chews:

- If you are allergic to any of the ingredients.
- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding") (see "HOW TO TAKE Releaf Probiotic kids chews").

Take special care with Releaf Probiotic kids chews:

Might cause gastrointestinal reactions.

Releaf Probiotic kids chews does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Keep away from children. Do not exceed the recommended dose.

Please consult your doctor or pharmacist prior to use if you:

- are having digestive tract surgery.
- have short bowel syndrome.
- are immunocompromised.

Taking Releaf Probiotic kids chews with food and drink:

There are no known side effects to taking **Releaf Probiotic kids chews** with food and drink.

Pregnancy and breastfeeding:

Do not use **Releaf Probiotic kids chews** 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 **Releaf Probiotic kids chews** would affect your ability to drive or use machinery. However, please exercise care until you are certain that your ability to perform such activities is not affected.

Important information about some of the ingredients of Releaf Probiotic kids chews:

Releaf Probiotic kids chews contains isomalt and may have a laxative effect.

Taking other medicines with Releaf Probiotic kids chews:

Always tell your healthcare professional if you are taking other medicines on a regular basis, including complementary or traditional medicines. The use of **Releaf Probiotic kids chews** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Do not take **Releaf Probiotic kids chews** in combination with medicines such as:

- Antibiotics (unless the probiotic is administered at least two hours after the antibiotic dose).
- Immunosuppressants such as cyclosporine, tacrolimus, azathioprine and cancer chemotherapeutic agents like cyclophosphamide and cisplatin.

HOW TO TAKE Releaf Probiotic kids chews:

The usual dose is:

Children ages 3 years and above: Chew 1 chew tablet daily.

It is advisable to stagger the administration of the antibiotic and probiotic such that the probiotic is administered at least two hours after the antibiotic dose, otherwise the antibiotic may reduce the efficacy of the probiotic microorganisms. Probiotics must be administered for at least one week following the completion of the antibiotic course.

If the symptoms worsen or persist, please consult your healthcare practitioner.

If you take more Releaf Probiotic kids chews than you should:

No known information on overdosage.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control center.

If you forget to take Releaf Probiotic kids chews:

Always take **Releaf Probiotic kids chews** 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 **Releaf Probiotic kids chews**"). Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

Releaf Probiotic kids chews can have side effects.

Not all side effects reported for **Releaf Probiotic kids chews** are included in this leaflet. Should your general health worsen while taking **Releaf Probiotic kids chews**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Releaf Probiotic kids chews and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Diarrhoea (*less frequent*).
- Bloating and flatulence (*less frequent*).

Please report/inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF Releaf Probiotic kids chews:

Store in a cool, dry place at or below 25 °C.

Protect from light. Do not remove the blisters from the original packing until required for use.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label. Return all unused **Releaf Probiotic kids chews** to your pharmacist.

Do not dispose of unused **Releaf Probiotic kids chews** in drains or sewerage systems (e.g. toilets).

PRESENTATION OF Releaf Probiotic kids chews:

Releaf Probiotic kids chews are available in PVC/aluminium blister strip, with each blister strip containing 10 chew tablets. Each carton of 10 chew tablets contains 1 blister strip and each carton of 30 chew tablets contains 3 blister strips.

IDENTIFICATION OF Releaf Probiotic kids chews:

A round pinkish/purple chewable tablet with a mixed berry flavour.

REGISTRATION NUMBER:

To be allocated.

Releaf Probiotic kids chews has not been evaluated by the SAHPRA for its quality, safety or intended use.

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

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PASIËNTINLIGTINGSBLAD

Inligting oor **Releaf Probiotic kids chews**

Gesondheidsaanvulling

SKEDULERNGSTATUS: **S0**

EIENDOMSNAAM EN DOSEERVORM:

Releaf Probiotic kids chews (koutablette).

Lees die hele inligtingsblad deeglik, want dit bevat belangrike inligting. **Releaf Probiotic kids chews** is beskikbaar sonder 'n dokter se voorskrif. U moet egter steeds **Releaf Probiotic kids chews** versigtig gebruik om die beste resultate daarmee te verkry.

Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
Moenie **Releaf Probiotic kids chews** met enige ander persoon deel nie.
Indien u verdere inligting of advies verlang, vra asseblief u apteker.
U moet 'n dokter raadpleeg indien u simptome vererger.

WAT Releaf Probiotic kids chews BEVAT:

Elke koutablet bevat:

Aktiewe bestanddele is:

1 biljoen KVE (kolonievormende eenhede) HOWARU® Bifido probiotika bestaan uit 'n mengsel van:

Bifidobacterium lactis; Bi-07®

Lactobacillus casei; Lc-11®

Lactobacillus acidophilus; La-14®

Die ander bestanddele is druiwedop ekstrakt, isomalt, magnesiumstearaat, sitroensuur, gemengde bessie geursel.

Bevat versoeter (20 mg CSA 80 (bevat kalium asesulfaan, natriumsakkarien en natriumsiklismaat)).

Suikervry.

WAARVOOR Releaf Probiotic kids chews GEBRUIK WORD:

Releaf Probiotic kids chews is 'n kombinasie van 3 probiotiese stamme wat help met die verbetering van die mikrobiële balans in die menslike dermkanaal en sodoende die funksionering van die spysverteringskanaal verbeter.

VOOR U Releaf Probiotic kids chews NEEM:

Moet NIE Releaf Probiotic kids chews neem NIE:

- Indien u allergies is vir enige van die bestanddele.
- Indien u swanger is of u baba borsvoed (see "Swangerskap en borsvoeding") (sien "HOE OM **Releaf Probiotic kids chews** TE GEBRUIK").

Neem spesiale sorg met Releaf Probiotic kids chews:

Kan gastro-intestinale reaksies veroorsaak.

Releaf Probiotic kids chews beoog nie om enige ongesteldheid of siektetoestand te genees nie en moet nie enige medikasie vervang nie. Mense wat aan 'n chroniese mediese toestand ly moet hulle gesondheidspraktisyn raadpleeg voor hulle hierdie produk gebruik. Hou buite bereik van kinders. Moenie die voorgeskrewe dosis oorskry nie.

Raadpleeg asseblief u dokter of apteker voor gebruik indien u:

- chirurgie aan die dermkanaal ondergaan het.
- kort-derm sindroom het.
- imuunonderdruk is.

Releaf Probiotic kids chews met kos en drinkgoed:

Daar is geen bekende nuwe-effekte om **Releaf Probiotic kids chews** saam met kos en drinkgoed te neem nie.

Swangerskap en borsvoeding:

Moenie **Releaf Probiotic kids chews** neem terwyl u swanger is of u baba borsvoed nie, aangesien die veiligheid hiervan nie bepaal is nie.

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker voor u hierdie medisyne neem.

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 **Releaf Probiotic kids chews** 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.

Belangrike inligting oor sommige van die bestanddele in Releaf Probiotic kids chews:

Releaf Probiotic kids chews bevat isomalt en kan die effek van 'n lakseermiddel hê.

Die neem van ander medisyne saam met Releaf Probiotic kids chews:

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde grondslag neem, insluitend komplementêre of tradisionele medisyne. Die gebruik van **Releaf Probiotic kids chews** saam met hierdie medisyne mag ongewenste wisselwerkings veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Moenie **Releaf Probiotic kids chews** in kombinasie met medisyne soos die volgende gebruik nie:

- Antibiotika (tensy die probiotika vir ten minste twee ure na die antibiotika geneem word).
- Immuno-ondridders soos siklosporien, takrolimus, asatioprien en kanker chemoterapeutiese middels soos siklofosfamied en sisplatin.

HOE OM Releaf Probiotic kids chews TE GEBRUIK:

Die gewone dosis is:

Kinders 3 jaar en ouer: Kou 1 koutablet daagliks.

Dit word aanbeveel om die toediening van die antibiotika en probiotika te versprei sodat die probiotika vir ten minste twee ure na die antibiotika geneem word, anders mag die antibiotika die effektiwiteit van die probiotiese mikroörganismes verminder. Probiotika moet vir ten minste een week na die voltooiing van die antibiotiese kursus geneem word.

As die simptome vererger of voortduur, raadpleeg 'n gesondheidsorgpraktisyn.

Indien u meer Releaf Probiotic kids chews geneem het as wat u moes:

Geen inligting bekend oor oordosering 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 Releaf Probiotic kids chews te neem:

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

MOONTLIKE NEWE-EFFEKTE:

Releaf Probiotic kids chews kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir **Releaf Probiotic kids chews** gemeld is, is in hierdie inligtingstuk gebruik nie. Indien u alseblief u dokter, apteker of ander professionele gesondheidsorgwerker gebruik, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, moet u die gebruik van Releaf Probiotic kids chews staak en u dokter dadelik in kennis stel of na die naaste ongevalle afdeling van die naaste hospitaal gaan:

- Diarree (*minder herhaaldelik*).
- Opgeblasenheid en winderigheid (*minder herhaaldelik*).

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

BERGING EN WEGDOEN VAN Releaf Probiotic kids chews:

Bewaar 'n koel, droë plek by of benede 25 °C.

Moenie die stolpverpakings uit die oorspronklike verpakings verwyder totdat dit nodig is vir gebruik nie.

HOU ALLE MEDISYNE BUTTE BEREIK VAN KINDERS.

Moenie gebruik na die vervaldatum op die etiket nie. Neem alle ongebruikte **Releaf Probiotic kids chews** na u apteker terug.

Moenie ongebruikte **Releaf Probiotic kids chews** in afvoertype of rioolsisteme (byvoorbeeld toilette) weggooi nie.

AANBIEDING VAN Releaf Probiotic kids chews:

Releaf Probiotic kids chews is beskikbaar in PVC/aluminium stolpverpakking, met elke stolpverpakking wat 10 koutablette bevat. Elke dosie bevat van 10 koutablette bevat 1 stolpverpakking en elke dosie van 30 koutablette bevat 3 stolpverpakings.

IDENTIFIKASIE VAN Releaf Probiotic kids chews:

'n Ronde pienk/pers koubare tablet met 'n gemengde bessie geur.

REGISTRASIENOMMER:

Sal toegeken word.

Releaf Probiotic kids chews is nie deur die Sahpra geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

NAAM EN SAKEADRES VAN DIE HOUER VAN DIE REGISTRASIE:

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RM



PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date: 3rd February 2018
Operator: Elizabeth Choudree
Customer: Afriplex
Product Name: Releaf Probiotic kids chews Leaflet
Product Code: PI RP0065/17A PIL RP0066/17A
Dimensions: 100 x 550 mm
Fold Size: 100 x 35 mm
Font Size: 6 point Times
Colours: (1) Black
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Barcode: --
Pharmacode: (Ref. 25) 0101
Stock: 45 gsm Pro-Thin
Proof Status: 2nd (Second)

Proof read by:

Reset: Alterations: Disk/Possie:

No alterations – proceed as soon as possible

Note alterations – Further proof is required

PLEASE CHECK CAREFULLY.

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

Signature:.....Date:.....

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Approved by R. Muller 05/02/2018 *RM*