

JUNGLEVITES PROBIOTIC CHEW

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

JUNGLEVITES PROBIOTIC CHEW, Chewable tablets
D 34.9 Complementary Medicine
Health Supplement-Probiotics
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.
Sugar free
Sweetener: Isomalt and Xylitol

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

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance. JUNGLEVITES PROBIOTIC CHEW is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use JUNGLEVITES PROBIOTIC CHEW carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not take a double dose to make up for forgotten individual doses.
- Ask your healthcare provider or pharmacist if you need more information or advice

What is in this leaflet

1. What is JUNGLEVITES PROBIOTIC CHEW and what it is used for
2. What you need to know before you take JUNGLEVITES PROBIOTIC CHEW
3. How to take JUNGLEVITES PROBIOTIC CHEW
4. Possible side effects
5. How to store JUNGLEVITES PROBIOTIC CHEW
6. Contents of the pack and other information

1. What is JUNGLEVITES PROBIOTIC CHEW and what it is used for

JUNGLEVITES PROBIOTIC CHEW is a health supplement that contains probiotics that:

- Helps balance and normalise gut flora
- Improves the functioning of the GUT
- Helps restore and maintain healthy gut flora
- Helps restore and maintain healthy vaginal flora
- Supports immune health
- A factor in the maintenance of good health

2. What you need to know before you take JUNGLEVITES PROBIOTIC CHEW

- Do not take JUNGLEVITES PROBIOTIC CHEW:
- If you are hypersensitive (allergic) to any of the ingredients.

Warnings and precautions

Special care should be taken with JUNGLEVITES PROBIOTIC CHEW. You should consult a healthcare provider prior to using JUNGLEVITES PROBIOTIC CHEW if you are immunocompromised (e.g. have AIDS, lymphoma or undergoing long-term corticosteroid treatment) since JUNGLEVITES PROBIOTIC CHEW might increase the risk of infection. If you experience fever, vomiting, bloody diarrhoea, or severe abdominal pain, consult a healthcare provider prior to using JUNGLEVITES PROBIOTIC CHEW.

If symptoms of digestive illness (e.g. diarrhoea) occur and/or persists beyond 3 days, discontinue use of the product and consult a healthcare provider.

Consult a relevant healthcare provider before use if you:

- have malabsorption or other GIT ailments or are having surgery; or
- are taking blood thinners, antibiotics or anti-inflammatory medication

If symptoms do not improve within seven days, consult a relevant healthcare provider.

Other medicines and JUNGLEVITES PROBIOTIC CHEW

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) Taking JUNGLEVITES PROBIOTIC CHEW with antibiotic medicines (e.g. amoxicillin) might decrease the effectiveness of the probiotics. Antibiotics might kill a significant number of the organisms from the probiotic if taken simultaneously. You should separate taking antibiotics and JUNGLEVITES PROBIOTIC CHEW by at least two hours.

JUNGLEVITES PROBIOTIC CHEW with food and drink and alcohol

For best results you should take a supplement 30 minutes prior to eating.

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 JUNGLEVITES PROBIOTIC CHEW. Safety during pregnancy and breastfeeding has not been established.

Driving and using machines

JUNGLEVITES PROBIOTIC CHEW may not affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

3. How to take JUNGLEVITES PROBIOTIC CHEW

Do not share medicines prescribed for you with any other person. Always take JUNGLEVITES PROBIOTIC CHEW as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual oral dose:

Adults and children older than 2 years:

Chew 1 tablet daily or as directed by a healthcare provider. Do not exceed the recommended daily dose without consulting a healthcare provider. For best results you should take a supplement 30 minutes prior to eating.

If you take more JUNGLEVITES PROBIOTIC CHEW than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take JUNGLEVITES PROBIOTIC CHEW

JUNGLEVITES PROBIOTIC CHEW, please consult your healthcare provider for advice.

4. Possible side effects

JUNGLEVITES PROBIOTIC CHEW can have side effects. Not all side effects reported for JUNGLEVITES PROBIOTIC CHEW are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking JUNGLEVITES PROBIOTIC CHEW, please consult your healthcare provider for advice.

If any of the following happens, stop taking JUNGLEVITES PROBIOTIC CHEW and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergy signs and symptoms: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to JUNGLEVITES PROBIOTIC CHEW. You may need urgent medical attention or hospitalisation. 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 or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of JUNGLEVITES PROBIOTIC CHEW.

5. How to store JUNGLEVITES PROBIOTIC CHEW

Store at or below 25°C.
KEEP OUT OF REACH OF CHILDREN.
Store in the original container.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
Do not use after the expiry date stated on the label / bottle.
Do not use JUNGLEVITES PROBIOTIC CHEW if you notice visible signs of deterioration.

6. Contents of the pack and other information

What JUNGLEVITES PROBIOTIC CHEW contains
The active substance is:

Lactobacillus reuteri 1 billion CFU

The other ingredients are:
Isomalt, Xylitol, Strawberry Flavourant, Magnesium Stearate, Citric acid.

What JUNGLEVITES PROBIOTIC CHEW looks like and contents of the pack

3 x 10 tablets in a single sealed blister, packed into a cardboard carton.

Holder of Certificate of Registration

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This leaflet was last revised in

TBA

Registration number

TBA

JUNGLEVITES PROBIOTIC CHEW

PASİENTİNİLGİTİNGİSLAADIJE

SKEDULERINGSTATUS

Ongeskeduleer

JUNGLEVITES PROBIOTIC CHEW, Koubare tablette
D 34.9 Komplementêre Medisyne:
Gesondheidsaanvulling: Probiotika
Hierdie ongeregistreerde medisyne is nie geëvalueer deur SAHPRA vir sy kwaliteit, veiligheid of beoogde gebruik nie.
Suikervry
Versoeter: Isomalt and Xylitol

Lees die hele inligtingsblaadjie noukeurig deur, dit bevat belangrike inligting vir jou

'n Dieël met verskeidenheid is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamstelling sowel as geestelike en fisiese prestasies te bewerkstellig. JUNGLEVITES PROBIOTIC CHEW is beskikbaar sonder 'n doktersvoorskrif om minder ernstige siektes te behandel. Jy moet egter nogsteeds JUNGLEVITES PROBIOTIC CHEW versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voorbeeld, dit mag dalk nodig wees om dit weer te lees
- Moenie JUNGLEVITES PROBIOTIC CHEW met enige ander persoon deel nie
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig

Wat is in hierdie pamflet

1. Wat JUNGLEVITES PROBIOTIC CHEW is en waarvoor dit gebruik word
2. Wat jy moet weet voor jy JUNGLEVITES PROBIOTIC CHEW neem
3. Hoe om JUNGLEVITES PROBIOTIC CHEW te neem
4. Moontlike newe-effekte
5. Hoe om JUNGLEVITES PROBIOTIC CHEW te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat JUNGLEVITES PROBIOTIC CHEW is en waarvoor dit gebruik word

- JUNGLEVITES PROBIOTIC CHEW is 'n gesondheidsaanvulling wat probiotik
- Help om dermflora te balanseer en normaliseer
 - Verbeter die funksionering van die GUT
 - Help om gesonde dermflora te herstel en in stand te hou
 - Help om gesonde vaginale flora te herstel en in stand te hou
 - Ondersteun immunisondheid
 - 'n Faktor in die handhawing van goeie gesondheid

2. Wat jy moet weet voor jy JUNGLEVITES PROBIOTIC CHEW neem

- Moet nie JUNGLEVITES PROBIOTIC CHEW neem:
- As jy hipersensitief (allergies) is vir enige van die bestanddele nie.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met JUNGLEVITES PROBIOTIC CHEW.
Jy moet 'n gesondheidsorgverskaffer raadpleeg voor die gebruik van JUNGLEVITES PROBIOTIC CHEW as jou immuun onderdruk is (bv. as jy VIGS of limfom het of langtermyn kortikosteroïed behandeling ondergaan) aangesien JUNGLEVITES PROBIOTIC CHEW die risiko vir infeksie kan verhoog.
Indien jy koors, braking, bloederige diarreë of erge abdominale pyn ondervind, moet jy jou gesondheidsorgverskaffer raadpleeg voordat jy JUNGLEVITES PROBIOTIC CHEW gebruik.
Indien simptome van spysverteringsongesteldheid (bv. diarreë) voorkom en/of dit vir langer as drie dae aanhou, moet jy die gebruik van die produk staak en jou gesondheidsorgverskaffer kontak.

Raadpleeg 'n relevante gesondheidsorgverskaffer voor gebruik as jy:

- wanabsorpsie of ander SVK-afwykings het of chirurgie ondergaan; of
- bloederdunners, antibiotika of anti-inflammatoriese medikasie neem

As simptome nie binne sewe dae verbeter nie, raadpleeg 'n relevante gesondheidsorgverskaffer.

Ander medisyne en JUNGLEVITES PROBIOTIC CHEW

Vertel altyd jou gesondheidsorgverskaffer as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.) Die neem van JUNGLEVITES PROBIOTIC CHEW saam met antibiotika (bv. amoksisillien) kan die doeltreffendheid van die probiotika verminder. Antibiotika kan 'n aansienlike aantal van die organismes in die probiotika doodmaak as dit gelyktydig geneem word. Jy moet die neem van antibiotika en JUNGLEVITES PROBIOTIC CHEW met ten minste twee ure skel.

JUNGLEVITES PROBIOTIC CHEW saam met kos en vloeistof en alkohol

Vir die beste resultate moet jy 'n aanvulling neem 30 minute voordat jy eet.

Swangerskap, borsvoeding en fertiliteit

As jy swanger is of borsvoed, dink jy mag dalk swanger wees of beplan om swanger te word, raadpleeg jou dokter, apteker of gesondheidsorgverskaffer vir advies voordat jy JUNGLEVITES PROBIOTIC CHEW neem. Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en die gebruik van masjiene

JUNGLEVITES PROBIOTIC CHEW mag dalk nie verstandelike en/of fisiese vermoëns beïnvloed om take of aktiwiteite uit te voer wat waaksaamheid, oordeel en/of gesonde koördinasie en visie vereis nie.

3. Hoe om JUNGLEVITES PROBIOTIC CHEW

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem JUNGLEVITES PROBIOTIC CHEW presies soos aanbeveel in hierdie pamflet of soos voorgeskryf deur jou dokter, apteker of verpleegster. Bevestig met jou dokter, apteker of verpleegster indien jy onseker is.

Die gewone orale dosis:

Volwassenes en kinders ouer as 2 jaar oud:

Kou 1 tablet daaglik of soos voorgeskryf deur 'n gesondheidsorgverskaffer.
Moet nie die aanbevole daaglikse dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie. Vir die beste resultate moet jy 'n aanvulling neem 30 minute voor ete.

As jy meer JUNGLEVITES PROBIOTIC CHEW neem as wat jy moet

In die geval van 'n oordosering, raadpleeg jou dokter of apteker. As geneem beskikbaar is nie, kontak die naaste gifteherseersterum.

As jy vergeet om JUNGLEVITES PROBIOTIC CHEW te neem

Moet nie 'n dubbele dosis neem om vir oorsagnesse dosisse te vergoed nie.

4. Moontlike newe-effekte

JUNGLEVITES PROBIOTIC CHEW kan newe-effekte hê. Nie alle newe-effekte wat vir JUNGLEVITES PROBIOTIC CHEW gearporteer is, is ingesluit in hierdie pamflet nie. As jou algemene gesondheid versleg of as jy ongewenste effekte ervaar met die neem van JUNGLEVITES PROBIOTIC CHEW raadpleeg jou gesondheidsorgverskaffer vir advies.

As enige een van die volgende gebeur, staak die gebruik van JUNGLEVITES PROBIOTIC CHEW en stel jou dokter onmiddellik in kennis of gaan na die naaste ongevalle afdeling by jou naaste hospitaal:

- Allergie tekens en simptome: swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat kan lei tot 'n probleem om te sluk of asem te haal, uitslag of jeuk

Hierdie is almal ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op JUNGLEVITES PROBIOTIC CHEW gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig. As jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel jou dokter of apteker in kennis.

Rapportering van newe-effekte

Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form" wat aanlyn onder SAHPRA se publikasies gevind kan word: <https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van JUNGLEVITES PROBIOTIC CHEW te verskaf.

5. Hoe om JUNGLEVITES PROBIOTIC CHEW te bewaar

Bewaar teen of benede 25°C.
HOU BUITE DIE BEREIK VAN KINDERS.
Bewaar in die oorspronklike houer.
Verskaf alle ongebruikte medisyne terug aan jou apteker.
Moet nie van ongebruikte medisyne ontsaak raak in dreine of rioolstelsel (bv. toilette) nie.
Moenie na die vervaldatum wat op die etiket / bottel aangedui is, gebruik nie.
Moenie JUNGLEVITES PROBIOTIC CHEW gebruik indien jy enige sigbare tekens van agteruitgang in die produk opmerk nie.

6. Inhoud van die verpakking en ander inligting

Wat JUNGLEVITES PROBIOTIC CHEW bevat
Die aktiewe bestanddeel is:

Lactobacillus reuteri 1 biljoen CFU

Die ander bestanddele is:
Isomalt, Xylitol, Aarbei geurmiddel, Magnesium Stearaat, Sitroensuur

Hoe JUNGLEVITES PROBIOTIC CHEW lyk en die inhoud van die verpakking

3 x 10 tablette in 'n enkel verseelde stulpstroom, verpak in 'n buiterste karton.

Houer van Sertifikaat van Registrasie

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Suid-Afrika
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Hierdie pamflet was hersien in

TBA

Registrasienommer

TBA

118229/00

JUNGLEVITES PROBIOTIC CHEW

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

1. NAME OF THE MEDICINE

JUNGLEVITES PROBIOTIC CHEW, Chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Lactobacillus reuteri 1 billion CFU

3. PHARMACEUTICAL FORM

Off-white chewable tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Helps balance and normalise gut flora
- Improves the functioning of the GUT
- Helps restore and maintain healthy gut flora
- Helps restore and maintain healthy vaginal flora
- Supports immune health
- A factor in the maintenance of good health

4.2 Posology and method of administration

Posology
Adults and children older than 2 years:
Chew 1 tablet daily or as directed by a healthcare provider. Do not exceed the recommended daily dose without consulting a healthcare provider. For best results you should take a supplement 30 minutes prior to eating.

Method of administration

Orally

4.3 Contraindications

Hypersensitivity (allergy) to any of the ingredients of JUNGLEVITES PROBIOTIC CHEW

Immunocompromised conditions (e.g. AIDS, lymphoma, patients undergoing long-term corticosteroid treatment).

4.4 Special warnings and precautions for use

Patients who suffer with fever, vomiting, bloody diarrhoea, or severe abdominal pain should consult a healthcare provider prior to use. Should symptoms of digestive upset (e.g. diarrhoea) occur and/or persist beyond 3 days, discontinue use and consult a healthcare provider. Consult a relevant healthcare provider before use if you

- have malabsorption or other GIT ailments or are having surgery; or
- are taking blood thinners, antibiotics or anti-inflammatory medication

4.5 Interaction with other medicines and other forms of interaction

Theoretically, taking JUNGLEVITES PROBIOTIC CHEW with antibiotic medicines (e.g. amoxicillin) might decrease the effectiveness of the probiotics. Antibiotics might kill a significant number of the organisms from the probiotic if taken simultaneously. Advise patients to separate taking antibiotics and JUNGLEVITES PROBIOTIC CHEW by at least two hours.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. 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 JUNGLEVITES PROBIOTIC CHEW.

4.7 Effects on ability to drive and use machines

JUNGLEVITES PROBIOTIC CHEW may not affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision

4.8 Undesirable effects

Side effects may include mild gastrointestinal upset and vaginal discharge.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Treatment should be symptomatic and supportive. In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

JUNGLEVITES PROBIOTIC CHEW is health supplement that contains probiotic. Lactobacillus are bacteria found in the human gastrointestinal tract. Supplementation with these bacteria restores normal microbial balance and reduces pathogenic bacteria.

When probiotics colonise the intestinal and urogenital mucosa, it seems to prevent epithelial attachment by pathogenic bacteria. This prevention may be partially related to the production of lactic acid.

Probiotics might have immunomodulating effects. Lactobacilli seem to modulate non-specific cellular and humoral immunity possibly by stimulating lymphocyte and macrophage activity and modulating cytokine production by mononuclear cells.

5.3 Preclinical safety data

JUNGLEVITES PROBIOTIC CHEW is safe when taken orally in doses below the tolerable upper intake level (UL). When used orally in excessive doses, can significantly increase the risk of adverse effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isomalt, Xylitol, Strawberry Flavourant, Magnesium Stearate, Citric acid.
Sugar free
Sweetener: Isomalt and Xylitol
Suitable for vegetarians

6.2 Incompatibilities

Unknown

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25°C.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

3 x 10 tablets in a single sealed blister, packed into a cardboard carton.

6.6 Special precautions for disposal and other handling

None

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ascendis Consumer Brands (Pty) Ltd
1 Carey Street
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+27 11 036 9420

8. REGISTRATION NUMBER(S)

TBA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

TBA

10. DATE OF REVISION OF THE TEXT

TBA

