

MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS

PATIENT INFORMATION LEAFLET

This leaflet tells you about MiBiotix AK ANTIBIOTIC THERAPY CHEWS.

Complementary medicine: Health Supplement.

SCHEDULING STATUS: S0

PROPRIETY NAME AND DOSAGE FORM:

MiBiotix AK ANTIBIOTIC THERAPY CHEWS (chewable tablets)

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

MiBiotix AK ANTIBIOTIC THERAPY CHEWS are available without a doctor's prescription. Nevertheless, you still need to use MiBiotix AK ANTIBIOTIC THERAPY CHEWS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MiBiotix AK ANTIBIOTIC THERAPY 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.

1. WHAT MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS CONTAINS:

2 Billion CFU's of <i>Bacillus subtilis</i> HU58
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2. WHAT MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS ARE USED FOR:

Your gut microflora is significantly reduced during and following antibiotic treatment. Your microflora plays an important role in your immune system as they act as the first line of defense in fighting bacteria and viruses. It is therefore important to replace these bacteria which also help prevent some of the common symptoms associated with antibiotic therapy (for example diarrhea, constipation, and intestinal cramps). *Bacillus subtilis* HU58 is a very robust probiotic that forms an outer protective shell, known as an endospore. This impenetrable coating protects the bacterium from harsh environments as it transits the gut, including heat, extreme pH levels, pressure, light, and lack of oxygen. The rugged nature of *Bacillus subtilis* HU58 makes it the perfect probiotic to survive and deliver 100% of its dose to the small intestine. *Bacillus subtilis* HU58 is even effective in the presence of broad-spectrum antibiotics and so it is safe to use in conjunction with other treatment protocols.

3. BEFORE YOU TAKE/ USE/ ARE GIVEN/ ADMINISTERED MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS:

Do NOT take/use MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

- If you are known to be hypersensitive (allergic) to (active ingredient) or any of the inactive ingredients.

Take special care with MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

MiBiotix AK ANTIBIOTIC THERAPY 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. Do not exceed the recommended dose.

Taking/ Using/ Receiving MiBiotix AK ANTIBIOTIC THERAPY CHEWS with food and drink:

MiBiotix AK ANTIBIOTIC THERAPY CHEWS should not be taken with milk, juice or any other fizzy drinks.

Driving and using machinery:

No studies on the effect on the ability to drive or use machinery have been performed. It is unlikely that MiBiotix AK ANTIBIOTIC THERAPY 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 MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

All inactive ingredients added on the formulation of MiBiotix AK ANTIBIOTIC THERAPY CHEWS are known to be well tolerated.

Taking/ Giving/ Using other medicines with MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

Always tell your healthcare professional if you are taking other medicines. (This includes complementary or traditional medicine). The use of MiBiotix AK ANTIBIOTIC THERAPY CHEWS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE/ USE MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS:

The usual dose is:

Take one MiBiotix AK Chew once daily after breakfast. Always take MiBiotix AK ANTIBIOTIC THERAPY CHEWS exactly as per recommendation of the Package Insert or by your health care provider and if you are unsure. If the symptoms worsen or persist, please consult your healthcare practitioner.

If you forget to take /miss a dose of MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

Always take MiBiotix AK ANTIBIOTIC THERAPY 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 MiBiotix AK ANTIBIOTIC THERAPY CHEWS"). Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

There has not been a case of any side effects reported when taking MiBiotix AK ANTIBIOTIC THERAPY CHEWS.

MiBiotix AK ANTIBIOTIC THERAPY CHEWS can have side effects.

Not all side effects reported for MiBiotix AK ANTIBIOTIC THERAPY CHEWS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MiBiotix AK ANTIBIOTIC THERAPY CHEWS, please consult your healthcare provider for advice.

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

6. STORAGE AND DISPOSING OF MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS:

Store all MiBiotix AK ANTIBIOTIC THERAPY CHEWS out of reach of children.

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

Keep the container in the original packaging and in an outer carton.

Protect from light.

Do not store in a bathroom.

Do not use after expiry date stated on the label/carton and on the bottle.

Do not use MiBiotix AK ANTIBIOTIC THERAPY CHEWS if you notice any visible signs of deterioration.

Return all unused MiBiotix AK ANTIBIOTIC THERAPY CHEWS to your pharmacist/supplier.

Do not dispose of unused MiBiotix AK ANTIBIOTIC THERAPY CHEWS in drains or sewage systems (e.g. toilets).

7. PRESENTATION OF MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS:

MiBiotix AK ANTIBIOTIC THERAPY CHEWS is packed in 10's, in a blister strip in an outer carton.

8. IDENTIFICATION OF MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS:

White chewable tablet.

9. REGISTRATION NUMBER:

Will be allocated by Council upon registration.

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

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Kenza Health (Pty) Ltd Suite 177, Private Bag X7, Northriding 2162
For professional information go to www.mibiotix.co.za

11. SCIENTIFIC SUPPORT

Current studies have shown that HU58 is one of the strains of *Bacillus subtilis* identified so far that can form spores, germinating into vegetative cells and grow in the anaerobic conditions of the human gastrointestinal tract thereby being able to create and maintain a useful microbial flora in the gut. This is particularly important for users of antibiotics because, following and during antibiotic treatment the resident population of gut microbes is significantly reduced. To replace these bacteria the consumption of harmless bacteria help to present some of the common symptoms associated with antibiotic therapy (for example diarrhea, constipation and intestinal cramps. When taken orally, spores of HU58 are extremely stable in the acidic conditions of the stomach. As such they can transit the stomach unscathed and can grow and germinate in the small intestine.

12. REFERENCES

Mazza P 1994. The use of *Bacillus subtilis* as an antidiarrheal microorganism Boll Chim Farmaceutico, 133:3-18

Hong et al 2009. *Bacillus subtilis* isolated from the human gastrointestinal tract. Res Microbial 160:134-143

Hong et al 2008 The safety of *Bacillus subtilis* and *Bacillus indicus* as food probiotics. Journal of Applied Microbiology 105:510-520

Cutting, S.M., 2011. *Bacillus* probiotics. Food Microbiol.28:214-220

MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS

PASIËNTINLIGTINGSBLAADJIE

Hierdie voubiljet bevat inligting oor MiBiotix AK ANTIBIOTIC THERAPY CHEWS.

Komplimentêre medisyne: Gesondheidsaanvulling.

BYLAE STATUS: S0

EIENDOMSNAAM (EN DOSISVORM):

MiBiotix AK ANTIBIOTIC THERAPY CHEWS (koutablette)

Lees die hele blaadjie sorgvuldig deur, want dit bevat belangrike inligting vir u.

MiBiotix AK ANTIBIOTIC THERAPY CHEWS is beskikbaar sonder die voorskrif van 'n dokter. U moet egter steeds MiBiotix AK ANTIBIOTIC THERAPY CHEWS versigtig gebruik om die beste resultate daarmee te verkry.

- Hou hierdie pamflet. Jy sal dit dalk weer moet lees.
 - Moenie MiBiotix AK ANTIBIOTIC THERAPY CHEWS met enige ander persoon deel nie.
 - Vra jou apteker as jy meer inligting of advies benodig.
 - U moet 'n dokter raadpleeg indien u simptome vererger of nie verbeter nie.

1. WAT MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS BEVAT:

2 Miljard KVE's van: *Bacillus subtilis*, HU58

2. WAARVOOR MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS GEBRUIK WORD:

Jou dermkanaalmikroflora verminder aansienlik tydens en ná antibiotiese behandeling. Jou mikroflora speel 'n belangrike rol in jou immuunstelsel, aangesien dit as die eerste verdedigingslinie in die bekamping van bakterieë en virusse dien. Dit is dus belangrik om hierdie bakterieë te vervang om te help met die voorkoming van algemene simptome wat met antibiotiese behandeling gepaard gaan (bv. diarree, hardlywigheid en dermkrampe).

Bacillus subtilis HU58TM is 'n uiters robuuste probiotikum wat 'n beskermende laag aan die buitekant vorm, bekend as 'n endospoor. Hierdie ondeurdringbare laag beskerm die bakterie van ongenaakbare omstandighede wanneer dit deur die dermkanaal gaan, insluitende hitte, uiterste pH-vlakke, druk, lig en 'n gebrek aan suurstof.

Die geharde aard van *Bacillus subtilis* HU58TM maak dit die perfekte probiotikum om te oorleef en 100% van sy dosis aan die dunderm te lewer. *Bacillus subtilis* HU58TM is selfs doeltreffend in die aanwesigheid van breëspektrum-antibiotika, dus is dit veilig om saam met ander behandelingsprotokolle te gebruik.

3. VOORDAT U MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS NEEM:

Moenie MiBiotix AK ANTIBIOTIC THERAPY CHEWS gebruik as:

- jy bewus is daarvan dat jy hipersensitief (allergies) is vir (aktiewe bestanddeel) of enige van die bestanddele.

Neem Spesiale sorg met MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

MiBiotix AK ANTIBIOTIC THERAPY 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. Moenie die voorgeskrewe dosis oorskry nie.

Die neem van MiBiotix AK ANTIBIOTIC THERAPY CHEWS met kos en drinkgoed:

MiBiotix AK ANTIBIOTIC THERAPY CHEWS moet nie saam met melk, sap of enige ander gaskoeldranke geneem word nie.

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 MiBiotix AK ANTIBIOTIC THERAPY 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 van MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

Al die onaktiewe bestanddele wat op die formulering van MiBiotix AK ANTIBIOTIC THERAPY CHEWS gevoeg word, word goed verdra.

Die neem van ander medisyne saam met MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

Lig altyd u gesondheidpraktisyn in wanneer u medisyne neem. (Dit sluit in komplementêre of tradisionele medisyne). Die gebruik van MiBiotix AK ANTIBIOTIC THERAPY CHEWS saam met hierdie medisyne mag ongewenste wisselwerkings veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

4. HOE OM MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS TE GEBRUIK

Die gewone dosis is:

Neem een MiBiotix AK ANTIBIOTIC THERAPY CHEWS tablet, daaglik na ontbyt.

Neem MiBiotix AK ANTIBIOTIC THERAPY CHEWS altyd volgens aanbevelings van die pakketinvoer of deur u gesondheidsorgverskaffer en indien u onseker is. As die simptome vererger of voortduur, raadpleeg 'n gesondheidsorgpraktisyn.

As u meer MiBiotix AK ANTIBIOTIC THERAPY CHEWS gebruik as wat u behoort:

Moenie meer as aanbevole dosis gebruik nie. (Sien pakketinvoegsel)

In die geval van 'n oordosis, raadpleeg u dokter of apteker. As geeneen van hulle beskikbaar is nie, kontak onmiddellik die naaste hospitaal of gifbeheersentrum.

As jy vergeet om 'n dosis MiBiotix AK ANTIBIOTIC THERAPY CHEWS te neem:

Neem MiBiotix AK ANTIBIOTIC THERAPY 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-nie, slaan die vergete dosis oor en keer terug na u gewone doseringskedule (sien "HOE OM MiBiotix AK ANTIBIOTIC THERAPY CHEWS TE GEBRUIK"). Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosis nie.

5. MOONTLIKE NEWE EFFEKTE

Daar was nie gevalle van enige neue-effekte gerapporteer wanneer MiBiotix AK ANTIBIOTIC THERAPY CHEWS geneem word nie.

MiBiotix AK ANTIBIOTIC THERAPY CHEWS kan neue-effekte hê.

Nie alle neue-effekte wat vir MiBiotix AK ANTIBIOTIC THERAPY CHEWS gemeld is, is in hierdie inligtingstuk vervat nie. Indien u algemene gesondheid agteruitgaan of u ongewenste wisselwerkings ervaar terwyl MiBiotix AK ANTIBIOTIC THERAPY CHEWS gebruik, raadpleeg asseblief u gesondheidsorgvoorsiener vir advies. Lig asseblief u dokter of apteker in indien u enige neue-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

6. BERGING EN WEGDOEN VAN MIBIOTIX AK ANTIBIOTIC THERAPY CHEWS:

Bewaar alle MiBiotix AK ANTIBIOTIC THERAPY CHEWS buite bereik van kinders.

Berg in 'n koel, droë plek onder of by 25 ° C.

Hou die houer in die oorspronklike verpakking en in 'n buitenste karton.

Beskerm teen lig.

Moenie in 'n badkamer stoor nie.

Moet nie gebruik word na die vervaldatum wat op die etiket / karton en op die bottel aangedui word nie.

Moenie MiBiotix AK ANTIBIOTIC THERAPY CHEWS gebruik as u enige sigbare tekens van agteruitgang sien nie.

Stuur alle ongebruikte MiBiotix AK ANTIBIOTIC THERAPY CHEWS na u apteker / verskaffer terug.

Moet nie ongebruikte MiBiotix AK ANTIBIOTIC THERAPY CHEWS in riool- of rioolstelsels gooi nie (byvoorbeeld toilette).

7. AANBIEDING VAN MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

MiBiotix AK ANTIBIOTIC THERAPY CHEWS is verpak in 10's, in 'n buitenste karton.

8. IDENTIFIKASIE VAN MiBiotix AK ANTIBIOTIC THERAPY CHEWS:

Wit koutablet.

9. REGISTRASIENOMMER:

Sal deur die Raad toegeken word by registrasie.

Hierdie ongeregisteerde medisyne is nie deur die SAHPRA geëvalueer ten opsigte van kwaliteit, veiligheid of beoogde gebruik nie.

10. NAAM EN ADRES VAN DIE HOUER VAN DIE REGISTRASIE:

Kenza Health (Edms) Bpk Suite 177, Private BagX7, Northriding 2162

Vir professionele inligting gaan na www.mibiotix.co.za

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