

Culturelle Capsules
Culturelle Chewtabs
Culturelle Paediatric Sachets

SCHEDULING STATUS:

Not applicable

PROPRIETARY NAME (AND DOSAGE FORM):

Culturelle capsules

Culturelle chewtabs (chewable tablet)

Culturelle paediatric sachets

COMPOSITION:

Each enteric coated capsule contains a minimum of 1×10^8 viable *Bifidobacterium longum* and *Lactobacillus rhamnosus* cells.

Alternatively known as lactic acid bacteria or probiotics.

Other ingredients: Fructo-oligosaccharides, glucose, potato starch and locus bean gum.

Each chew tablet contains a minimum of 1×10^8 viable *Bifidobacterium longum* and *Lactobacillus rhamnosus* cells which have been microencapsulated with natural protein.

Alternatively known as lactic acid bacteria or probiotics.

Other ingredients: Oligosaccharides, lactic acid, magnesium stearate and tangerine flavour and odour.

Each 1,5 g sachet contains a minimum of 1×10^8 viable *Bifidobacterium longum*, *Lactobacillus acidophilus* and *Streptococcus thermophilus* cells which have been microencapsulated.

Alternatively known as lactic acid bacteria or probiotics.

Other ingredients: Oligosaccharides, silicon dioxide and magnesium stearate.

PHARMACOLOGICAL CLASSIFICATION:

A: 34 Other

PHARMACOLOGICAL ACTION:

Probiotics compete with pathogenic bacteria for enteric sites (within the intestine) thereby inhibiting the pathogenic bacteria from establishing themselves.

Furthermore, probiotics compete with pathogenic bacteria for nutrients thereby inhibiting the pathogenic bacteria from multiplying (proliferating) and becoming the dominant bacteria.

INDICATIONS:

To assist in restoring the intestinal flora imbalance caused by factors such as diarrhoea, bacterial infections, stress, travelling, antibiotic treatment, alcohol consumption, poor diet and other factors.

CONTRA-INDICATIONS:

No known contra-indications.

DOSAGE AND DIRECTIONS FOR USE:

Capsule and Chewtab:

PREVENTATIVE: 1 capsule or chew tablet twice a day.

During ANTIBIOTIC TREATMENT: 2 capsules or chew tablets twice a day.

Paediatric sachet:

PREVENTATIVE:

Children under 1 year: Administer the contents of 1 (one) sachet mixed in water or milk twice a day.

Children over 1 year: Administer the contents of 2 (two) sachets mixed in water or milk twice a day.

During ANTIBIOTIC TREATMENT:

Children under 1 year: Administer the contents of 2 (two) sachets mixed in water or milk twice a day.

Children over 1 year: Administer the contents of 4 (four) sachets mixed in water or milk twice a day.

While receiving oral antibiotic therapy, it is recommended that **Culturelle** be taken 3 hours after the antibiotic.

Or as directed by your Healthcare Professional

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

No known side-effects.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No known symptoms of overdosage.

IDENTIFICATION:

Culturelle capsules:	Opaque white to off-white hard gelatine capsule.
Culturelle chewtabs:	Round, off-white, yellow speckled biconvex tablet.
Culturelle paediatric sachets:	White to off-white powder having a characteristic odour and flavour.

PRESENTATION:

Culturelle capsules:	Containers of 15 and 30 capsules
Culturelle chewtabs:	Containers of 15 and 30 chewtabs
Culturelle Paediatric sachet:	Boxes of 15 sachets each containing 1,5 g.

STORAGE INSTRUCTIONS:

Store in a cool place (below 25°C).

Keep out of reach of children.

NAME AND BUSINESS ADDRESS:

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Culturelle Chewtabs
Culturelle Paediatric Sachets

SKEDULERINGSSTATUS:

Nie van toepassing nie.

EIENDOMSNAAM (EN DOSEERVORM):

Culturelle capsules
Culturelle chewtabs (*koutablet*)
Culturelle paediatric sachets (sakkie).

SAMESTELLING:

Elke enteries-bedekte kapsule bevat 'n minimum van 1×10^8 lewensvatbare *Bifidobacterium longum* en *Lactobacillus rhamnosus* selle.
Alternatief bekend as melksuurbakterieë of probiotika.
Ander bestanddele: Frukto-oliegosakkariede, glukose, aartappelstysel en Johannesburggom.

Elke *koutablet* bevat 'n minimum van 1×10^8 lewensvatbare *Bifidobacterium longum* en *Lactobacillus rhamnosus* selle wat deur natuurproteïen mikroverkapsel is.
Alternatief bekend as melksuurbakterieë of probiotika.
Ander bestanddele: Oliegosakkariede, laktiensuur, magnesiumstearaat en nartjierooi- smaak en geur.

Elke 1,5 g sakkie bevat 'n minimum van 1×10^8 lewensvatbare *Bifidobacterium longum*, *Lactobacillus acidophilus* en *Streptococcus thermophilus* wat mikroverkapsel is.
Alternatief bekend as melksuurbakterieë of probiotika.
Ander bestanddele: Oliegosakkariede, silisiumdioksied en magnesiumstearaat.

FARMAKOLOGIESE KLASSIFIKASIE:

A: 34 Ander.

FARMAKOLOGIESE WERKING:

Probiotika kompeteer met patogene bakterieë vir enteriese setels (binne die ingewande), wat inhibeer dat die patogene bakterieë hulself kan vestig. Probiotika kompeteer ook met patogene bakterieë vir voedingstowwe en inhibeer dat die patogene bakterieë vermenigvuldig (proliferasie) en die dominante bakterieë word.

INDIKASIES:

Om versteurings in die balans van die intestinale flora wat veroorsaak word deur faktore soos bv. diaree, bakteriële infeksies, stres, reise, behandeling met antibiotika, alkoholiname, swak dieët en ander faktore te herstel.

KONTRA-INDIKASIES:

Geen teenaanduidings is bekend nie.

DOSERING EN GEBRUIKSAANWYSINGS:

Kapsule en Koutablet

VOORKOMEND: 1 kapsule of *koutablet* twee keer per dag.

Tydens BEHANDELING MET ANTIBIOTIKA: 2 kapsules of koutablette twee keer per dag.

Pediatrics sakkie:

VOORKOMEND:

Kinders onder 1 jaar: Administreer die inhoud van 1 (een) sakkie gemeng met water of melk twee keer per dag.

Kinders ouer as 1 jaar: Administreer die inhoud van 2 (twee) sakkies gemeng met water of melk twee keer per dag

Tydens BEHANDELING MET ANTIBIOTIKA:

Kinders onder 1 jaar: Administreer die inhoud van 2 (twee) sakkies gemeng met water of melk twee keer per dag.

Kinders ouer as 1 jaar: Administreer die inhoud van 4 (vier) sakkies gemeng met water of melk twee keer per dag.

Terwyl orale antibiotika terapie ontvang word, word dit aanbeveel dat

Culturelle 3 uur na die antibiotikum geneem word.

Of soos deur Gesondheidsorgpersoneel voorgeskryf.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Geen newe-effekte is bekend nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Geen simptome van oordosering is bekend nie.

IDENTIFIKASIE:

Culturelle capsules:	Opake wit tot naaswit, harde gelatienkapsule.
Culturelle chewtabs:	Rond, naaswit, geel gespikkelde bikonveks tablet.
Culturelle paediatric sachets:	Wit tot naaswit poeier met 'n karakteristiek geur en smaak.

AANBIEDING:

Culturelle capsules:	Houers met 15 en 30 kapsules.
Culturelle chewtabs:	Houers met 15 en 30 koutablette.
Culturelle paediatric sachets:	Karton van 15 sakkies wat elk 1,5 g bevat.

BERGINGSANWYSINGS:

Bewaar in 'n koel plek (benede 25°C).

Hou buite bereik van kinders.

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