PACKAGE INSERT **COLIX INFANT DROPS**	**VOUBILJET** **COLIX INFANT DROPS**
SCHEDULING STATUS S0	**SKEDULERINGSTATUS** S0
PROPRIETARY NAME AND DOSAGE FORM **COLIX INFANT DROPS** (5 ml liquid)	**HANDELSNAAM EN DOSEERVORM** **COLIX INFANT DROPS** (5 ml vloeistof)
COMPOSTION Each 5 ml contains : Lactase Enzyme	**SAMESTELLING** Eike 5ml bevat : Laktase Ensiem
Excipients: Glycerol, purified water	**Onaktiewe bestanddele:** Gliserol, gesuiwerde water.
PHARMACOLOGICAL CLASSIFICATION D. Health supplement	**FARMAKOLOGIESE KLASSIFIKASIE** D. Gesondheids aanvulling
PHARMACOLOGICAL ACTION **COLIX INFANT DROPS** contains a purified lactase enzyme preparation. Lactase enzyme hydrolyses the milk sugar lactose into two monosaccharides, glucose and galactose. It is known that, due to low intestinal lactase activity, not all babies are able to digest the lactose in milk with the same ease. Lactose intolerance is common in the following cases: • Babies with transient lactase deficiency • Premature birth • Undernourished children Research has identified transient lactase deficiency as one of the factors in babies with infantile colic. Undigested lactose is broken down by bacteria in the colon, producing hydrogen gas which causes the bloating and pain referred to as colic. Similar research has identified breath hydrogen as a marker of hypolactasis. Breath hydrogen is significantly reduced after treatment with lactase enzyme compared with placebo.	**FARMAKOLOGIESE WERKING** **COLIX INFANT DROPS** bevat 'n gesuiwerde laktase ensiem. Die laktase ensiem hidroliseer die melksuiker, laktase in twee monosakkariede, glukose en galaktose. Dit is bekend dat, as gevolg van lae derm laktase aktiwiteit, kan alle babas nie die laktase in melk met dieselfde gemak verteer nie. Laktase onverdraagsaamheid is algemeen in die volgende gevalle : • Babas met 'n tekort aan laktase (verbygaande tekort) • premature geboorte • ondervoede kinders Navorsing het 'n laktase tekort (verbygaande tekort) geidentifiseer as een van die faktore in babas met infantiele koliek. Onverteerde laktase word deur bakteriee in die kolon afgebreek, dit veroorsaak die vervaardiging van waterstofgas wat opgeblaasheid en pyn veroorsaak wat na verwys word as koliek. Soortgelyke navorsing wys dat asem waterstof as 'n merker van hypolaktasia geidentifiseer kan word. Asem waterstof is aansienlik verminder na behandeling met laktase ensiem in vergelyking met 'n placebo.
INDICATIONS **COLIX INFANT DROPS** contains lactase enzyme and is used as a supplement to support and assist the digestion of lactose in breast milk and formula.	**INDIKASIES** **COLIX INFANT DROPS** bevat laktase ensiem en word gebruik as 'n aanvulling om die vertering van laktase in bors melk en formule te ondersteun en te help.
CONTRA-INDICATIONS Do not use if you are hypersensitive (allergic) to any of the other ingredients of **COLIX INFANT DROPS**. Tell your doctor if are not sure about any of the above.	**KONTRA-INDIKASIES** Moet nie gebruik as jy hipersensitief (allergies) is vir enige van die bestanddele van **COLIX INFANT DROPS** nie. Raadpleeg jou dokter as jy nie seker is nie.
WARNINGS AND SPECIAL PRECAUTIONS Enzymes are destroyed by excessive heat. **COLIX INFANT DROPS** works best in warm milk. Always follow the instructions carefully when making up formula milk. Do not add **COLIX INFANT DROPS** to milk that is too hot or too cold. **Effects on ability to drive vehicles and use machines:** Not relevant	**WAARSKUWINGS EN SPESIALE VOORSORGMAATREELS** Ensieme word deur oormatige hitte vernietig. **COLIX INFANT DROPS** werk die beste in warm melk, volg altyd die instruksies noukeurig vir die aanmaak van die melk formule. Moet nie **COLIX INFANT DROPS** by melk wat te warm of te koud is byvoeg nie. **Effek op die vermoë om motor te bestuur en masjinerie te gebruik:** nie van toepassing
INTERACTIONS None known	**INTERAKSIES** Geen bekend
PREGNANCY AND LACTATION The safety of **COLIX INFANT DROPS** in pregnancy has not been established.	**SWANGERSKAP EN LAKTASIE** Die veiligheid van **COLIX INFANT DROPS** in swangerskap is nie vasgestel nie.
DOSAGE AND DIRECTIONS FOR USE **Breastfeeding** • Express about 10ml of breast milk into a container. • Add 2 drops of **COLIX INFANT DROPS** to this breast milk. • Administer to baby with a spoon. • Breastfeed baby as normal. • **COLIX INFANT DROPS** may be administered with 10 ml water in place of the 10ml breast milk referred to above. • Breast feed as normal. **Infant formula** • Make up formula as per instructions. • Add 2 drops **COLIX INFANT DROPS** per 90 ml (formula should be warm) • Allow to stand for 30 minutes, shaking occasionally. • Feed baby as per normal.	**DOSIS EN GEBRUIKSAANWYSINGS** **Borsvoeding** • Neem 10 ml borsmelk en plaas in 'n houer. • Voeg 2 druppels **COLIX INFANT DROPS** by die borsmelk. • Gee vir die baba met 'n lepel. • Borsvoed die baba soos gewoonlik. • **COLIX INFANT DROPS** kan met 10 ml water toegedien word in die plek van die 10 ml borsmelk. **Baba formule** • Maak formule aan soos per die instruksies. • Voeg 2 druppels C**OLIX INFANT DROPS** per 90 ml formule (formule moet warm wees) • Laat staan vir 30 minute, skud af en toe. • Voer baba soos gewoonlik.
SIDE EFFECTS None known **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT** Treatment should be symptomatic and supportive. (See side effects).	**NEWE-EFFEKTE** Geen bekend **BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN** Behandeling moet simptomaties en ondersteunend wees. (Sien newe effekte).
IDENTIFICATION A clear to light-brown viscous liquid	**IDENTIFIKASIE** 'n Deursigtige tot ligte-bruin viskose vloeistof.
PRESENTATION Plastic dropper bottle containing 5 ml liquid.	**AANBIEDING** Plastiek drupper bottel met 5 ml vloeistof.
STORAGE INSTRUCTIONS Store at or below 25°C Take care to keep below 25°C during transportation. Refrigerate after opening. Keep in original packaging until required for use. Do not use after the expiry date printed on the bottle. **KEEP OUT OF REACH OF CHILDREN**.	**BERGINGSINSTRUKSIES** Bewaar teen of onder 25°C. Sorg dat dit tydens vervoer onder 25°C gehou word. Verkoel na oopmaak. Hou in oorspronklike verpakking. Moet nie na die vervaldatum gebruik nie. **HOU BUITE BEREIK VAN KINDERS.**
REGISTRATION NUMBER Will be allocated by Council upon registration.	**REGISTRASIENOMMER** Sal toegeken word deur die Raad na afloop van registrasie.
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION Keynote Health (Pty) Ltd. Unit 2 Penny Lane Park 64 Ebonyfield Ave Springfield Park 4091	**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT** Keynote Health (Pty) Ltd Unit 2 Penny Lane Park 64 Ebonyfield Ave Springfield Park 4091
DATE OF PUBLICATION OF THE PACKAGE INSERT October 2017	**DATUM VAN PUBLIKASIE VAN DIE VOUBILJET** Oktober 2017
This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.	Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie. Hierdie medisyne beoog nie om enige siekte te diagnoseer, te behandel, te genees of te voorkom nie.

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PATIENT INFORMATION LEAFLET
COLIX INFANT DROPS

PASIENTINLIGTINGSBLAADJIE
COLIX INFANT DROPS

SCHEDULING STATUS
S0

SKEDULERINGSTATUS
S0

PROPRIETARY NAME AND DOSAGE FORM
COLIX INFANT DROPS (5ml liquid)

HANDELSNAAM EN DOSEERVORM
COLIX INFANT DROPS (5ml vloeistof)

Read all of this leaflet carefully because it contains important information for you.
COLIX INFANT DROPS is available without a doctor's prescription. However, you still need to use **COLIX INFANT DROPS** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **COLIX INFANT DROPS** with any other person.
- Ask your pharmacist if you need more information or advice.

Lees die hele voubiljet noukeurig deur, want dit bevat belangrike inligting vir jou.
COLIX INFANT DROPS is beskikbaar sonder 'n voorskrif. Nogtans moet jy die gebruiksaanwysings vir **COLIX INFANT DROPS** noukeurig volg om die beste resultate te verkry.

- Hou hierdie voubiljet. Jy mag dit dalk weer moet lees.
- Moet nie **COLIX INFANT DROPS** met enige ander persoon deel nie.
- Vra jou apteker indien jy meer inligting of advies nodig het.

WHAT COLIX INFANT DROPS CONTAINS
Each 5 ml contains:
Lactase Enzyme
The other ingredients are: Glycerol, purified water

WAT COLIX INFANT DROPS BEVAT
Elke 5 ml bevat:
Laktase Ensiem
Die ander bestanddele is: Gliserol, gesuiwerde water

WHAT COLIX INFANT DROPS IS USED FOR
COLIX INFANT DROPS contains lactase enzyme and is used as a supplement to support and assist the digestion of lactose in breast milk and formula.

WAARVOOR COLIX INFANT DROPS GEBRUIK WORD
COLIX INFANT DROPS bevat laktase ensiem en word gebruik as 'n aanvulling om die vertering van laktase in borsmelk en formule te ondersteun en help.

BEFORE YOU TAKE COLIX INFANT DROPS
Do not take COLIX INFANT DROPS

- If you are hypersensitive (allergic) to any of the ingredients.

Tell your doctor if you are not sure about any of the above.

Take special care with COLIX INFANT DROPS

- If you have a history of allergic reactions.

T**aking COLIX INFANT DROPS with food and drink:** Not relevant

VOORDAT JY COLIX INFANT DROPS GEBRUIK
Moet nie COLIX INFANT DROPS gebruik:

- Indien jy hipersensitief (allergies) is vir enige van die bestanddele.

Raadpleeg jou dokter indien jy nie seker is oor enige van bogenoemde nie.

Neem spesiale voorsorg met COLIX INFANT DROPS

- As jy 'n geskiedenis van allergiese reaksies het.

Die neem van COLIX INFANT DROPS met kos en drank: Nie toepaslik

Pregnancy and lactation
If you are pregnant, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Effects on ability to drive vehicles and use machinery: Not known

Important information about some of the ingredients in COLIX INFANT DROPS
Taking other medicines with COLIX INFANT DROPS

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

Swangerskap en laktasie
As jy swanger is, raadpleeg jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy hierdie medisyne neem.

Effek op die vermoé om motor te bestuur en masjinerie te gebruik: Nie bekend

Belangrike inligting oor die bestanddele in COLIX INFANT DROPS
Gebruik van ander medisyne saam met COLIX INFANT DROPS

Vertel jou gesondheidsorg professionele as jy enige ander medisyne gebruik. (insluitend aanvullende of tradisionele medisyne.)

HOW TO TAKE COLIX INFANT DROPS
Do not share medicines with any other person. Always take **COLIX INFANT DROPS** exactly as indicated or as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:
Breastfeeding

- Express about 10ml of breast milk into a container or spoon.
- Add 2 drops of **COLIX INFANT DROPS** to this breast milk.
- Administer to baby with a spoon.
- Breastfeed baby as normal thereafter.
- **COLIX INFANT DROPS** may be administered with 10 ml water in place of the 10 ml breast milk referred to above.
- **COLIX INFANT DROPS** may be administered before each and every feed.

Infant formula

- Make up formula as per instructions
- Add 2 drops **COLIX INFANT DROPS** per 90ml formula (formula should be warm)
- Allow to stand for 30 minutes, shaking occasionally
- Feed baby as per normal.
- **COLIX INFANT DROPS** may be administered before each and every feed.

If you take more COLIX INFANT DROPS than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

I**f you forget to take / missed a dose of COLIX INFANT DROPS**

Take your missed dose with the next feed. Do not take a double dose with the next feed to make up for forgotten individual doses.

Effects when treatment with COLIX INFANT DROPS is stopped
If taking the dose as indicated, then there should be no adverse effects when stopping use of this medication.

POSSIBLE SIDE EFFECTS
COLIX INFANT DROPS has no known side effects
Not all side effects reported for **COLIX INFANT DROPS** are included in this leaflet. Should your baby experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

HOE OM COLIX INFANT DROPS TE NEEM
Moet nie jou medisyne met enige ander persone deel nie.
Neem **COLIX INFANT DROPS** altyd presies soos aangedui of soos deur jou dokter voorgeskryf.
Raadpleeg jou dokter of apteker indien jy onseker is.

Die normale dosis is:
Borsvoeding

- Neem 10 ml borsmelk en plaas in 'n houer.
- Voeg 2 druppels **COLIX INFANT DROPS** by die borsmelk.
- Gee vir die baba met 'n lepel.
- Borsvoed die baba soos gewoonlik.
- **COLIX INFANT DROPS** kan met 10 ml water toegedien word in die plek van die 10 ml borsmelk.
- **COLIX INFANT DROPS** kan voor elke voed toegedien word.

Baba formule

- Maak formule aan soos per die instruksies.
- Voeg 2 druppels **COLIX INFANT DROPS** per 90 ml formule (formule moet warm wees).
- Laat staan vir 30 minute, skud af en toe.
- Voer baba soos gewoonlik.
- Moet nie meer as die aanbevole dosis neem nie.
- **COLIX INFANT DROPS** kan voor elke voed toegedien word.

As jy meer COLIX INFANT DROPS neem as wat jy behoort
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As jy vergeet/nagelaat het om 'n dosis van COLIX INFANT DROPS te neem.

Neem die oorgeslaande dosis met die volgende voeding. Moet nie 'n dubbele dosis met die volgende voeding neem om op te maak vir individuele dosisse wat jy oorgeslaan het nie.

Uitwerking na behandeling met COLIX INFANT DROPS gestaak is:
Indien die dosis soos aangedui geneem word, sal daar geen newe-effekte wees wanneer die gebruik van **COLIX INFANT DROPS** gestaak word nie.

MOONTLIKE NEWE-EFFEKTE
COLIX INFANT DROPS het geen bekende newe-effekte nie.
Nie alle newe-effekte aangemeld vir **COLIX INFANT DROPS** is in hierdie pamflet ingesluit nie. Indien jou baba se algemene gesondheid verswak of as jy ongewenste effekte ervaar terwyl jy die medisyne gebruik, raadpleeg jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

STORING AND DISPOSING OF COLIX INFANT DROPS
Store at or below 25°C.
Take care to keep below 25°C during transport.
Refrigerate after opening.
Protect from light.
Keep in original packaging until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the label or box.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

HOE OM COLIX INFANT DROPS TE STOOR EN DAARVAN ONTSLAE TE RAAK
Bewaar teen of onder 25°C.
Sorg dat dit tydens vervoer onder 25°C gehou word.
Verkoel na oopmaak.
Beskerm teen lig en vog.
Bewaar in die oorspronklike verpakking.
Moet nie in 'n badkamer stoor nie.
Moet nie na die vervaldatum op die karton/bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of
rioolstelsels (bv. toilette) weggooi nie.
HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

PRESENTATION OF COLIX INFANT DROPS
Plastic dropper bottle containing 5 ml liquid

AANBIEDING VAN COLIX INFANT DROPS
Plastiek drupper bottel met 5 ml vloeistof

IDENTIFICATION OF COLIX INFANT DROPS
A clear to pale brown viscous liquid

IDENTIFIKASIE VAN COLIX INFANT DROPS
'n Deursigtige tot ligte bruin viskose vloeistof

REGISTRATION NUMBER
Will be allocated by Council upon registration.

REGISTRASIENOMMER
Sal toegeken word deur die Raad na afloop van registrasie.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
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DATE OF PUBLICATION OF THE PACKAGE
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Oktober 2017

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