

PROFESSIONAL INFORMATION COLIX INFANT DROPS	PROFESIONELE INLIGTING 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 (B-galactoside) 3000 ALU's /g min Contains no sugar	SAMESTELLING Eike 5 ml bevat : Laktase Ensiem (B-galactoside) 3000 ALU's /g min Bevat geen suiker
Excipients: Glycerol, purified water	Onaktiewe bestanddele: Gliserol, gesuiwerde water
CATEGORY Complementary medicine D34.5 Enzymes	KATEGORIE Komplementêre medisyne D34.5 Enzieme
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 hypolactasia. 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) geïdentifiseer as een van die faktore in babas met infantiele koliek. Onverteerde laktase word deur bakterieë 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 geïdentifiseer 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 VOORSORGMATREELS 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 10 ml 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 10 ml 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 (formula should be warm) - Allow to stand for 30 minutes, shaking occasionally. - Feed baby as per normal. - Colix infant drops should be administered before each and every feed.	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 COLIX INFANT DROPS per 90 ml formule (formule moet warm wees) - Laat staan vir 30 minute, skud af en toe. - Voer baba soos gewoonlik. - Colix infant drops kan voor elke voed toegedien word.
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. 6 Heron Park 80 Corobrik Road Riverhorse Valley Durban 4017	NAAM EN BESIGHEIDSAADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT Keynote Health (Pty) Ltd 6 Heron Park 80 Corobrik Road Riverhorse Valley Durban 4017
DATE OF PUBLICATION OF THE PACKAGE INSERT February 2022	DATUM VAN PUBLIKASIE VAN DIE VOUBILJET Februarie 2022
This unregistered medicine has not been evaluated by the SAHPRA for it's quality, safety or intended use.	Hierdie ongeregistreerde medisyne was nie deur die SAHPRA geëvalueer vir kwaliteit, veiligheid of gebruiks intensies.

PATIENT INFORMATION LEAFLET COLIX INFANT DROPS	PASIENTINLIGTINGSBLAADJIE 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)
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 (B-galactoside) 3000 ALU's /g min The other ingredients are: Glycerol, purified water Contains no sugar	WAT COLIX INFANT DROPS BEVAT Elke 5 ml bevat: Laktase Ensiem (B-galactoside) 3000 ALU's /g min Die ander bestanddele is: Gliserol, gesuiwerde water Bevat geen suiker
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. Taking 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 vermoë 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 10 ml 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 90 ml 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 overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. If 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
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