PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

Oramico Gel

Oral Gel

20 mg miconazole per gram

Contains alcohol: 7,6 mg ethanol (96 %) per gram.

Contains sweetener: 1 mg sodium saccharin per gram.

Read all of this leaflet carefully because it contains important information for you.
Oramico Gel is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Oramico Gel carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **Oramico Gel** 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.

What is in this leaflet

1. What **Oramico Gel** is and what it is used for
2. What you need to know before you use **Oramico Gel**
3. How to use **Oramico Gel**
4. Possible side effects
5. How to store **Oramico Gel**
6. Contents of the pack and other information.

1. What Oramico Gel is and what it is used for
Oramico Gel contains the active ingredient miconazole.
Oramico Gel is used for treating fungal infections of the mouth (e.g. thrush in babies four months and older and oral candidiasis in other age groups) and for fungal infections of the mouth occurring in association with dentures.

2. What you need to know before you use Oramico Gel
Do not use Oramico Gel
- if you are hypersensitive (allergic) to miconazole, or any of the other ingredients of **Oramico Gel** (listed in section 6)
- in infants less than 4 months of age or in premature infants less than 6 months old or in those with swallowing reflex not yet fully developed, because of the risk of choking
- if you or your child have any kind of liver disease
- if you are taking any other medicines unless you have consulted your health care provider (see **Other medicines and Oramico Gel** below).

Warnings and precautions
Take special care with Oramico Gel
Avoid contact with the eyes.

Bleeding disorders
If you experience unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in your urine, black tarry stools or coffee ground vomit, stop treatment with **Oramico Gel** and contact your health care provider immediately.

Infants and small children
Oramico Gel is sticky. This ensures that it stays in the mouth for as long as possible. If you are giving **Oramico Gel** to a child or infant, make sure that the gel does not close off the child's or infant's throat as they could choke on it. You should place **Oramico Gel** at the front of the mouth – never put it at the back of the throat.
It is important to be aware of your infant's ability to swallow, especially when giving **Oramico Gel** to infants between the ages of 4 – 6 months. If your baby was born prematurely, do not use **Oramico Gel** below the age of 6 months.

Serious skin reactions
If you experience any signs of serious skin reactions (e.g. toxic epidermal necrolysis or Stevens-Johnson syndrome): painful, red or purple skin, peeling or blistering of skin, the use of **Oramico Gel** should be discontinued at the first appearance of skin rash.

Other medicines and Oramico Gel
Always tell your health care provider if you are using any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following:
- medicines to prevent clotting of the blood (anticoagulants), such as warfarin
- medicines used to treat epilepsy (fits/seizures), called phenytoin or carbamazepine
- medicines used to treat diabetes taken by mouth (sulphonylureas), such as chlorpropamide or glibenclamide
- medicines used to treat hay fever or allergy, called terfenadine, astemizole or mizolastine
- medicines used to treat digestive problems, called cisapride
- medicines used to treat an irregular heart beat called, quinidine, dofetilide or disopyramide
- medicines used to treat conditions affecting thoughts, feelings and behaviour, called pimozide or sertindole
- medicines used to treat migraine, called ergotamine
- medicines used to lower cholesterol, called lovastatin or simvastatin
- medicines used to treat anxiety or to help you sleep, called midazolam or triazolam
- medicines used to treat HIV infection, called saquinavir
- medicines used in the treatment of cancer, such as busulfan, docetaxel and a group of medicines known as "vinca alkaloids"
- medicines that act on the heart and blood vessels called calcium channel blockers, such as dihydropyridines and verapamil
- medicines that are usually given after an organ transplant called ciclosporin, tacrolimus or sirolimus (also called rapamycin)
- medicines used to improve the symptoms of a certain blood flow problem in the legs (intermittent claudication), called cilostazol
- medicines used for anxiety or to help you sleep (tranquillisers), such as buspirone, alprazolam or brotizolam
- medicine used to treat pain, called alfentanil
- medicine used to treat erection problems, called sildenafil
- medicine used to treat tuberculosis (TB), called rifabutin
- medicine used to treat inflammation (given by mouth or injection), called methylprednisolone
- medicine used to treat a type of pneumonia, called trimetrexate
- medicine used to treat allergy, called ebastine
- medicine used to treat depression, called reboxetine.

Pregnancy and breastfeeding
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 health care provider for advice before using **Oramico Gel.**

You should not use **Oramico Gel** if you are pregnant or breastfeeding.
If you are breastfeeding your baby, do not apply **Oramico Gel** to your nipple for administration to your baby due to the risk of choking.

Driving and using machines
Oramico Gel is not likely to affect your ability to drive a vehicle or use any tools or machines.

Important information about some of the ingredients of Oramico Gel
- **Oramico Gel** contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".
- **Oramico Gel** contains 0,0076 g of alcohol (ethanol) in each 1 g which is equivalent to 0,0076 mg/mg (0,76 % *m/m*). The amount in 1 g is equivalent to less than 1 mL beer or 1 mL wine. The small amount of alcohol in Oramico Gel will not have any noticeable effects.

3. How to use Oramico Gel
Do not share medicines prescribed for you with any other person.

Recommended dosages:
Full term infants: 4 – 24 months: 1,25 mL (¼ measuring spoon) of gel, applied four times a day after meals. Each dose is to be divided into smaller portions and the gel applied to the affected area(s) with a clean finger. Adults and children 2 years and older: 2,5 mL (½ measuring spoon) of gel, applied four times a day after meals.
Always use **Oramico Gel** exactly as your doctor or pharmacist has instructed you.
You should check with your doctor or pharmacist if you are unsure.
Oramico Gel should not be swallowed immediately, but kept in the mouth as long as possible.
Spread evenly over the affected areas, taking care to properly cover oral ulcerations and other lesions.
Apply **Oramico Gel** regularly until all signs of the infection have disappeared.
Continue using for another two days after the infection has cleared.
Apply **Oramico Gel** preferably after meals.
Thus, **Oramico Gel** can remain in contact with the mouth for a longer period.
If you have a fungal infection in your mouth (stomatitis), you should apply **Oramico Gel** to the lesions in the evening and leave on overnight.
If you have oral candidiasis and are wearing dentures, you should preferably remove them at bedtime and brush them with **Oramico Gel.** In this way, you can prevent your dentures from becoming infected too.

If you use more Oramico Gel than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any **Oramico Gel** left or not.

If you forget to use Oramico Gel
If you forget to apply a dose, apply it as soon as you remember. Do not apply a double dose to make up for forgotten individual doses.

4. Possible side effects
Oramico Gel can have side effects.
Not all side effects reported for **Oramico Gel** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **Oramico Gel,** please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using Oramico Gel and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **Oramico Gel.** You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- choking
- yellowing of the skin and eyes, dark urine and tiredness, which may be symptoms of liver problems
- severe skin disorders with peeling and/or rashes with small pus-containing pimples (with a fever) or blistering of your skin, mouth, eyes and genitals (toxic epidermal necrolysis or Stevens-Johnson syndrome).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- dry mouth
- nausea (feeling sick)
- vomiting (being sick)
- mouth discomfort
- regurgitation (bringing up swallowed food to the mouth)
- abnormal product tastes.

Less frequent side effects:
- dysgeusia (taste disorder).

Unknown side effects:
- diarrhoea
- stomatitis (painful swelling and sores inside the mouth)
- tongue discolouration
- rash with pus filled pimples/blisters (acute generalised exanthematous pustulosis)
- drug reaction with eosinophilia and systemic symptoms (DRESS syndrome, characterised by fever, rash, abnormal blood tests, swollen lymph nodes).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **Oramico Gel.**

5. How to store Oramico Gel
- Store at or below 30 °C. Protect from light.
- Keep the tube tightly closed until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What Oramico Gel contains
The active substance is miconazole.
Each gram of **Oramico Gel** contains 20 mg miconazole.

Other ingredients are polysorbate 20, pregelatinised potato starch, glycerine, sodium saccharin, ethanol 96 %, pineapple flavour, purified water.

What Oramico Gel looks like and contents of the pack
White to off-white homogenous translucent oral gel, with pineapple taste and free from any gritty particles.
Aluminium tube containing 30 g gel, with white HDPE piercing screw cap, packed in an outer carton.

Holder of Certificate of Registration
LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6
10 Church Street
Durbanville
7551
087 551 3245

This leaflet was last revised in
Date of Registration: 4 February 2025
Date of Revision: Not Applicable

Registration number
57/20.2.2/0035

Access to the corresponding Professional Information
Request via the email address: info@lebasi.co.za

LP0045/0002

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400 mm

150 mm

PASIËNTINLIGTINGSBLAD

SKEDULERING STATUS

S2

Oramico Gel

Orale Jel

20 mg mikonasool per gram

Bevat alkohol: 7,6 mg etanol (96 %) per gram.

Bevat versoeter: 1 mg natriumsakkarien per gram.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.
Oramico Gel is beskikbaar sonder 'n dokter se voorskrif, sodat jy 'n ligte ongesteldheid kan behandel. Jy moet **Oramico Gel** nogtans versigtig gebruik om die beste resultate daarmee te verkry.
- Hou hierdie inligtingsblad. Dit mag nodig wees om dit later weer te lees.
- Moenie **Oramico Gel** met enigiemand anders deel nie.
- Vra jou apteker indien jy nog inligting of raad nodig het.
- Jy moet 'n dokter gaan sien indien jou simptome vererger of nie verbeter nie.

Wat is in hierdie inligtingsblad

1. Wat is **Oramico Gel** en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy **Oramico Gel** gebruik
3. Hoe om **Oramico Gel** te gebruik
4. Moontlike newe-effekte
5. Hoe om **Oramico Gel** te bewaar
6. Inhoud van die verpakking en ander inligting.

1. Wat is Oramico Gel en waarvoor word dit gebruik
Oramico Gel bevat die aktiewe bestanddeel mikonasool.
Oramico Gel word gebruik vir die behandeling van swaminfeksies in die mond (bv. sproei by babas vier maande en ouer, en orale kandidiase by ander ouderdomsgroepe) en vir swaminfeksies in die mond waar valstande gedra word.

2. Wat jy moet weet voordat jy Oramico Gel gebruik
Moenie Oramico Gel gebruik nie
- indien jy hipersensitief (allergies) vir mikonasool, of vir enige van die ander bestanddele van **Oramico Gel** is (gelys by afdeling 6)
- by babas jonger as 4 maande oud of by premature babas jonger as 6 maande oud, of by dié waar die slukrefleks nog nie ten volle ontwikkel het nie, weens die risiko van verstikking
- indien jy of jou kind enige soort lewersiekte het
- indien jy enige ander medisynes neem, behalwe as jy jou gesondheidsorgverskaffer daaroor geraadpleeg het (sien **Ander medisynes en Oramico Gel** hier onder).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met Oramico Gel
Vermy kontak met die oë.

Bloedingsversteurings
Indien jy onverwags bloeding of kneusing, neusbloeding, hoes van bloed, bloed in jou urine, taai swart ontlasting of braaksel wat soos koffiemoer lyk ondervind, staak behandeling met **Oramico Gel** en kontak onmiddellik jou gesondheidsorgverskaffer.

Babas en klein kindertjies
Oramico Gel is taai. Dit verseker dat dit so lank as moontlik in die mond bly. Indien jy **Oramico Gel** vir 'n kind of baba gee, maak seker dat die jel nie die kind of baba se keel blokkeer nie aangesien dit hulle kan laat verstik. Jy moet **Oramico Gel** aan die voorkant van die mond aanwend – moet dit nooit agter in die keel plaas nie.
Dit is belangrik om bewus te wees van jou baba se slukvermoë, veral wanneer **Oramico Gel** aan babas tussen die ouderdom van 4 en 6 maande gegee word. Indien jou baba prematuur gebore is, moenie **Oramico Gel** voor die ouderdom van 6 maande gebruik nie.

Ernstige velreaksies
Indien jy enige tekens van ernstige velreaksies ontwikkel (bv. toksiese epidermale nekrolise of Stevens-Johnsonsindroom) soos pynlike, rooi of pers vel, vel wat afskilfer of blase vorm, moet die gebruik van **Oramico Gel** met die eerste verskyning van so 'n veluitslag gestaak word.

Ander medisynes en Oramico Gel
Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)

Sê vir jou dokter indien jy enige van die volgende gebruik:
- medisynes om stolling van die bloed te voorkom (antikoagulante), soos warfarien
- medisynes gebruik om epilepsie (toevalle/stuiptrekkings) te behandel, genaamd fenitoïen of karbamasepien
- medisynes wat vir diabetes per mond geneem word (sulfonielureums), soos chloorpropamied of glibenklamied
- medisynes gebruik om hooikoors of allergie te behandel, genaamd terfenadien, astemisool of misolastien
- medisyne gebruik om spysverteringsprobleme te behandel, genaamd sisapried
- medisynes gebruik om 'n onegalige hartklop te behandel, genaamd kinidien, dofetilied of disopiramied
- medisynes gebruik om toestande te behandel wat jou gedagtes, gevoelens en gedrag affekteer, genaamd pimosied of sertindool
- medisyne gebruik om migraine (skeelhoofpyn) te behandel, genaamd ergotamien
- medisynes gebruik om cholesterol te verlaag, genaamd lovastatien of simvastatien
- medisynes gebruik om angstigheid te behandel of om jou te help om te slaap, genaamd midasolaam of triasolaam
- medisynes gebruik om MIV-infeksie te behandel, genaamd sakinavir
- medisynes gebruik in die behandeling van kanker, soos busulfaan, dosetaksel en 'n groep medisynes bekend as "Vinca-alkaloïede"
- medisynes wat op die hart en bloedvate inwerk, genaamd kalsiumkanaalblokkers, soos dihidropiridiene en verapamiel
- medisynes wat gewoonlik ná 'n orgaanoorplanting gegee word, genaamd siklosporien, takrolimus of sirolimus (ook rapamisien genoem)
- medisyne gebruik om die simptome van 'n sekere bloedvloeiprobleem in die bene (intermitterende kloudikasie) te verbeter, genaamd silostasool
- medisynes gebruik vir angstigheid of om jou te help om te slaap (kalmeermiddels), soos buspiroon, alprasolaam of brotisolaam
- medisyne gebruik om pyn te behandel, genaamd alfentaniel
- medisyne gebruik om ereksieprobleme te behandel, genaamd sildenafiel
- medisyne gebruik om tuberkulose (TB) te behandel, genaamd rifabutien
- medisyne gebruik om inflammasie te behandel (per mond of met 'n inspuiting gegee), genaamd metielprednisoloon
- medisyne gebruik om 'n soort longontsteking te behandel, genaamd trimetreksaat
- medisyne gebruik om allergie te behandel, genaamd ebastien
- medisyne gebruik om depressie te behandel, genaamd reboksetien.

Swangerskap en borsvoeding
Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of gesondheidsorgverskaffer voordat jy **Oramico Gel** gebruik.

Moenie **Oramico Gel** gebruik indien jy swanger is of borsvoed nie.
Indien jy jou baba borsvoed, moenie **Oramico Gel** aan jou tepel aanwend om dit so aan jou baba toe te dien nie, weens die gevaar van verstikking.

Bestuur en gebruik van masjiene
Dit is onwaarskynlik dat **Oramico Gel** jou vermoë om 'n voertuig te bestuur of enige gereedskap of masjiene te gebruik, gaan aantas.

Belangrike inligting oor party van die bestanddele van Oramico Gel
- **Oramico Gel** bevat minder as 1 mmol natrium (23 mg) per dosis, dit is dus wesenlik natriumvry.
- **Oramico Gel** bevat 0,0076 g alkohol (etanol) in elke 1 g wat gelykstaande is aan 0,0076 mg/mg (0,76 % *m/m*). Die hoeveelheid in 1 g is gelykstaande aan minder as 1 mL bier of 1 mL wyn. Die klein hoeveelheid alkohol in **Oramico Gel** gaan nie enige opsigtelike effekte hê nie.

3. Hoe om Oramico Gel te gebruik
Moenie medisynes wat vir jou voorgeskryf is, met enigiemand anders deel nie.
Aanbevole doserings:
Voltermynbabas: 4 – 24 maande: 1,25 mL (¼ maatlepel) jel, vier keer per dag na etes aangewend. Elke dosis moet in kleiner dele verdeel word en die jel moet met 'n skoon vinger aan die aangetaste area(s) aangewend word. Volwassenes en kinders 2 jaar en ouer: 2,5 mL (½ maatlepel) jel, vier keer per dag ná ete aangewend.
Gebruik **Oramico Gel** altyd presies soos wat jou dokter of apteker vir jou aangedui het.
Vra gerus jou dokter of apteker indien jy onseker is.
Oramico Gel moenie dadelik ingesluk word nie, maar vir so lank as moontlik in die mond gehou word.
Versprei eweredig oor die aangetaste areas en sorg dat die ulserasies en ander letsels in die mond behoorlik bedek word.
Wend **Oramico Gel** gereeld aan, totdat alle tekens van die infeksie verdwyn het.
Hou vir nog twee dae nadat die infeksie opgeklaar het aan om dit te gebruik.
Wend **Oramico Gel** verkieslik ná etes aan. Sodoende kan **Oramico Gel** vir 'n langer tydperk in kontak met die mond bly.
Indien jy 'n swaminfeksie in jou mond het (stomatitis), wend **Oramico Gel** saans aan die letsels en hou dit oornag so.
Indien jy orale kandidiase het en valstande dra, verwyder dit verkieslik teen slapenstyd en borsel dit met **Oramico Gel.** Sodoende kan jy keer dat jou valstande ook geïnfekteer word.

Indien jy meer Oramico Gel gebruik as wat jy moet
In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem altyd die medisynepakkie waarop die etiket is saam, of daar enige **Oramico Gel** oor is of nie.

Indien jy vergeet om Oramico Gel te neem
Indien jy vergeet het om 'n dosis aan te wend, gebruik dit sodra jy onthou. Moenie 'n dubbele dosis aanwend om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

4. Moontlike newe-effekte
Oramico Gel kan newe-effekte hê.
Nie alle newe-effekte wat vir **Oramico Gel** gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien jy enige ongunstige effekte ondervind terwyl jy **Oramico Gel** neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg.

Indien enige van die volgende voorkom, hou op om Oramico Gel te gebruik en sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk en asemhaling kan veroorsaak
- uitslag of gejeuk
- floute.

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ondervind, mag jy 'n ernstige reaksie op **Oramico Gel** gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Indien jy enige van die volgende opmerk, sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- verstikking
- vergeling van die vel en die oë, donker urine en moegheid, wat simptome van lewerprobleme kan wees
- hewige velversteurings met afskilfering en/of uitslag met klein ettergevulde puisies (met koors) of blaasvorming op jou vel, mond, oë en geslagsdele (toksiese epidermale nekrolise of Stevens-Johnsonsindroom).

Hierdie is ernstige newe-effekte. Jy mag dringend mediese sorg benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- droë mond
- naarheid (voel mislik)
- braking (gooi op)
- ongemak in die mond
- regurgitasie (voedsel vloei terug uit jou maag na jou mond)
- abnormale smaak in die mond.

Newe-effekte wat minder dikwels voorkom:
- disgeusie (smaakversteuring).

Newe-effekte waarvan die frekwensie onbekend is:
- diarree
- stomatitis (pynlike swelling en sere binne in die mond)
- verkleuring van die tong
- uitslag met etterpuisies/blase (akute algemene eksanteemagtige pustulose)
- medisynereaksie met eosinofilie en sistemiese simptome (DRESS-sindroom, gekenmerk deur koors, uitslag, abnormale bloedtoetse, geswolle limfknope).

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker daaroor in.

Rapportering van newe-effekte:
Indien jy enige newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en eRapportering-platform (who-umc.org), wat op SAHPRA se webwerf beskikbaar is. Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van **Oramico Gel** te verskaf.

5. Hoe om Oramico Gel te bewaar
- Bêre by of onder 30 °C. Beskerm teen lig.
- Hou die buis dig toe tot nodig vir gebruik.
- BEWAAR ALLE MEDISYNES BUITE BEREIK VAN KINDERS.
- Moenie gebruik ná die vervaldatum wat op die karton gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die verpakking en ander inligting
Wat Oramico Gel bevat
Die aktiewe bestanddeel is mikonasool.
Elke gram **Oramico Gel** bevat 20 mg mikonasool.
Ander bestanddele is polisorbaat 20, voorafgegelatineerde aartappelstysel, gliserien, natriumsakkarien, etanol 96 %, pynappelgeursel en gesuiwerde water.

Hoe Oramico Gel lyk en inhoud van die verpakking
Wit tot naaswit, homogene, deurskynende mondelikse jel, met 'n pynappelsmaak en sonder enige korrelrige deeltjies.
Aluminiumbuis wat 30 g jel bevat, met 'n wit HDPE-skroefprop wat 'n gaatjie kan deurdruk, verpak in 'n buitenste karton.

Houer van Registrasiesertifikaat
LeBasi Pharmaceuticals (Edms.) Bpk
San Domenico-gebou, Eenheid 6
Kerkstraat 10
Durbanville
7551
087 551 3245

Hierdie inligtingsblad is laas hersien
Datum van registrasie: 4 Februarie 2025
Datum van hersiening: Nie van toepassing nie

Registrasienommer: 57/20.2.2/0035

Toegang tot die ooreenstemmende Professionele Inligting
Versoek deur e-pos te stuur aan: info@lebasi.co.za

LP0045/0002

xxxx

Product Name : Oramico_Gel_PI	**Item : Insert**	**Date : 25_15/04__26/03/25**
Co-ordinator : Kishori	**Artist : NITIN**	
Language : English / AFRIKAANS		
Actual Size : 150 x 400 mm (L x H)_Folding Size :		
Colours : Black		
Reference Artwork item code: xxx	**EPP No.: xxx**	**CCF No.: xxx**
Leaflet : **J. K. Maplitho 60 GSM** **Folding Size**		
If any Special instruction Instructions: **Any deviation must be brought to the notice of packaging development co-ordinator immediately.**		

Checked by	R.A.	B.H.	F n D	PDC
A/w Initiation date:				
A/w Final date:				