

JUNGLEVITES GUMMY C

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

JUNGLEVITES GUMMY C, gummy, 100 mg
Ascorbic Acid (Vitamin C)
Contains sugar(s): Glucose syrup 0,6 g; Sucrose 1,0 g
Category D Complementary Medicine
Discipline 34.11 Health Supplements. Multiple substance formulation
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use

Read all of this leaflet carefully because it contains important information for you
JUNGLEVITES GUMMY C is available without a doctor's prescription, for you to maintain your' health. Nevertheless, you still need to use JUNGLEVITES GUMMY C carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Do not share JUNGLEVITES GUMMY C with any other person
- Ask your healthcare provider or pharmacist if you need more information or advice

What is in this leaflet

- What JUNGLEVITES GUMMY C is and what it is used for
- What you need to know before you take JUNGLEVITES GUMMY C
- How to take JUNGLEVITES GUMMY C
- Possible side effects
- How to store JUNGLEVITES GUMMY C
- Contents of the pack and other information

1. What JUNGLEVITES GUMMY C is and what it is used for
JUNGLEVITES GUMMY C is a health supplement that contains vitamin C, which support the immune system.
JUNGLEVITES GUMMY C provides support during high risk times, winter and seasonal changes.
Vitamin C help reduce the severity and duration of symptoms of cold and flu.
Maintenance of good health.
Contributes to iron absorption from food.
Helps to metabolise fats and proteins.
Contributes to normal collagen formation for the normal function of blood vessels, bones, cartilage, gums, skin and teeth.

2. What you need to know before you take JUNGLEVITES GUMMY C
Do not take JUNGLEVITES GUMMY C:

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

Other medicines and JUNGLEVITES GUMMY C
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and Breastfeeding
If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking JUNGLEVITES GUMMY C. JUNGLEVITES GUMMY C is not safe for use during pregnancy and while breastfeeding.

Important information about some of the ingredients of JUNGLEVITES GUMMY C
JUNGLEVITES GUMMY C contains glucose syrup and sucrose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking JUNGLEVITES GUMMY C. JUNGLEVITES GUMMY C contains glucose, which may have an effect on the glycaemic control of patients with diabetes mellitus.
JUNGLEVITES GUMMY C contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take JUNGLEVITES GUMMY C
Always take JUNGLEVITES GUMMY C exactly as described in this leaflet or as your doctor, or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.
Do not share medicines prescribed for you with any other person.
The usual dose is:
Children 4 years and older: Take 1 - 2 gummies once daily after food or as recommended by your healthcare practitioner.
Do not exceed the recommended daily dosage without consulting a healthcare practitioner

If you take more JUNGLEVITES GUMMY C than you should:
You might experience abdominal cramps, esophagitis, heartburn, headache, osmotic diarrhea, nausea and vomiting.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take JUNGLEVITES GUMMY C
Do not take a double dose to make up for forgotten individual doses

4. POSSIBLE SIDE EFFECTS
JUNGLEVITES GUMMY C can have side effects.
Not all side effects reported for JUNGLEVITES GUMMY C are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking JUNGLEVITES GUMMY C , please consult your healthcare provider for advice.
Most common adverse effects that are more likely to occur at doses above the tolerable upper intakelevel of 2 grams daily are: abdominal cramps, esophagitis, heartburn, headache, osmotic diarrhea, nausea, vomiting.
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 or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form" , found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/index/6. By reporting side effects, you can help provide more information on the safety of JUNGLEVITES GUMMY C .

5. How to store JUNGLEVITES GUMMY C
KEEP OUT OF REACH OF CHILDREN.
Store at or below 25 °C.
Store in the original package / container.
Keep the container tightly closed.
Protect from moisture.
Store away from direct sunlight
Keep it in a dry place
Do not store in a bathroom.
Do not use after the expiry date stated on the label / bottle.
Do not use JUNGLEVITES GUMMY C if you notice visible signs of deterioration.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information
What JUNGLEVITES GUMMY C contains
Active substance is:

Ascorbic Acid (Vitamin C) 100 mg

The other ingredients are glucose syrup, sugar, pectin, water, naartjie flavour, beta-carotene colour

What JUNGLEVITES GUMMY C looks like and contents of the pack
A translucent orange colour animal shaped gummy with a fruity scent. Packed in a 250ml PET brown container and closed with black childproof lid. Packed in an outer carton.

Marketed by
Ascendis Consumer Brands (Pty) Ltd
Wynberg, Gauteng 2090
South Africa
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This leaflet was last revised in
TBA

Registration number
RSA: TBA

Access to the corresponding Professional Information

JUNGLEVITES GUMMY C

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSSTATUS
Ongeskeduleer

JUNGLEVITES GUMMY C, gummie, 100 mg
Askerbiersuur (Vitamin C)
Bevat suiker(s): Glukose stroop 0,6 g; Sukrose 1,0 g
Kategorie D Komplementêre Medisyne
Dissipline 34.11 Gesondheidsaanvullings. Veelvoudige substans formulering
Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy kwaliteit, veiligheid of beoogde gebruik nie.

Lees die hele inligtingsblaadjie noukeurig deur, dit bevat belangrike inligting vir jou
JUNGLEVITES GUMMY C is beskikbaar sonder 'n doktersvoorskrif om minder ernstige siektes te behandel. Jy moet egter nogsteeds JUNGLEVITES GUMMY C versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voublajet, dit mag dalk nodig wees om dit weer te lees.
- Moet nie JUNGLEVITES GUMMY C met enige ander persoon deel nie.
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig.

Wat is in hierdie voublajet

- Wat JUNGLEVITES GUMMY C is en waarvoor dit gebruik word
- Wat jy moet weet voor jy JUNGLEVITES GUMMY C neem
- Hoe om JUNGLEVITES GUMMY C te neem
- Moontlike newe-effekte
- Hoe om JUNGLEVITES GUMMY C te bewaar
- Inhoud van die verpakking en ander inligting

1. Wat JUNGLEVITES GUMMY C is en waarvoor word dit gebruik
JUNGLEVITES GUMMY C is 'n gesondheidsaanvulling wat vitamien C bevat, wat die immuunsistiem ondersteun.
JUNGLEVITES GUMMY C bied ondersteuning tydens tye van hoë risiko, winter en seisoenale veranderinge.
Vitamien C help om die erns en duur van verkoue- en griepsimptome te verminder.
Dra by tot die instandhouding van goeie gesondheid.
Help met die absorpsie van yster uit voedsel.
Help met die metabolisme van vette en proteïene.
Dra by tot normale kollageenvorming vir die normale funksie van bloedvate, bene, kraakbeen, tandvleis, vel en tande.

2. Wat jy moet weet voor jy JUNGLEVITES GUMMY C neem
Moet nie JUNGLEVITES GUMMY C gebruik indien:

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

Ander medisyne en JUNGLEVITES GUMMY C
Vertel altyd jou gesondheidsorgverskaffer as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in)

Swangerskap en Borsvoeding
As jy swanger is of jou baba borsvoed, raadpleeg jou gesondheidsorg-verskaffer voordat jy JUNGLEVITES GUMMY C gebruik.
JUNGLEVITES GUMMY C is nie veilig vir gebruik tydens swangerskap of borsvoeding nie.

Belangrike inligting in verband met sommige van die bestanddele in JUNGLEVITES GUMMY C
JUNGLEVITES GUMMY C bevat glukose stroop en sukkrose.
As jy deur jou dokter vertel is dat jy 'n intoleransie vir sommige suiker het, kontak jou dokter voordat jy JUNGLEVITES GUMMY C neem.
JUNGLEVITES GUMMY C bevat glukose wat 'n effek op die beheer van jou bloedsuiker kan hê as jy diabetes mellitus het.
JUNGLEVITES GUMMY C bevat sukkrose wat 'n effek op die beheer van jou bloedsuiker kan hê as jy diabetes mellitus het.

3. Hoe om JUNGLEVITES GUMMY C te neem
Neem JUNGLEVITES GUMMY C altyd presies soos voorgeskryf in hierdie voublajet of soos voorgeskryf deur jou dokter, apteker of verpleegster.
Bevestig met jou dokter of apteker indien jy onseker is.
Moenie jou medisyne met enige iemand anders deel nie
Die gewone dosis is:
Kinders 4 jaar en ouer:
Neem 1 - 2 gummies eenkeer daaglik na ete of soos voorgestel deur jou gesondheidsorgverskaffer.
Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorg-praktisyn te raadpleeg nie.

As jy meer JUNGLEVITES GUMMY C neem as wat jy moet
Jy mag dalk abdominale krampe, esofagitis, sootbrand, hooptyn, osmotiese diarree, nasaaiheid en braking ervaar.
Indien ondorsening vermoed word, raadpleeg onmiddellik jou dokter of apteker. Indien geneene beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Indien jy vergeet het om JUNGLEVITES GUMMY C te neem.
Moenie 'n dubbele dosis neem om vir oorgestane dosisse te vergoed nie.

4. MOONTLIKE NEWE-EFFEKTE
JUNGLEVITES GUMMY C kan newe-effekte hê.
Nie alle newe-effekte wat vir JUNGLEVITES GUMMY C aangemeld is, word in hierdie voublajet genoem nie. Indien jou algemene gesondheid verswak of indien jy enige nadelige effekte ondervind tenwyl jy JUNGLEVITES GUMMY C neem, moet jy asselblief jou gesondheidsorgverskaffer vir advies raadpleeg.
Mees algemene newe-effekte wat meer geneig is om voor te kom by dosisse bo die aanvaarbare boonste innamevlak van 2 gram per dag, sluit in: Abdominale krampe, esofagitis, sootbrand, hooptyn, osmotiese diarree, nasaaiheid en braking.

As jy enige newe-effekte opmerk wat nie in hierdie voublajet genoem word nie, stel asseblief jou dokter of apteker in kennis.

Rapportering van newe-effekte
As jy newe-effekte ondervind, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form" wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/index/6. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van BETTAWAY VIT C GUMMIES te verskaf.

5. Hoe om JUNGLEVITES GUMMY C te stoor
HOU BUITE BEREIK VAN KINDERS
Bewaar teen of benede 25 °C.
Stoor in die oorspronklike verpakking/houer.
Hou die houer dig toe.
Beskerm teen vog.
Stoor weg van direkte sonlig.
Stoor in 'n droë plek.
Moet nie die produk in die badkamer stoor nie.
Moet nie na die vervaldatum wat op die etiket / bottel aangedui is, gebruik nie.
Moet nie JUNGLEVITES GUMMY C gebruik indien jy enige sigbare tekens van produktraak opmerk nie.
Besorg enige ongebruikte medisyne terug aan jou apteker.
Moet nie van ongebruikte medisyne ontslae raak in dreine of rioolstelsels nie (bv. toilette).

6. Inhoud van die verpakking en ander inligting
Wat JUNGLEVITES GUMMY C bevat
Aldiewe bestanddeel is: Askorbienuur (Vitamien C) 100 mg

Die ander bestanddele is glukose stroop, suiker, pektien, water, nartjie geur, beta-karoteen kleursel.

Hoe JUNGLEVITES GUMMY C voorkom en inhoud van die verpakking
'n Deursigtige, oranje gekleurde diervormige gummie met 'n vrugte reuk. Verpak in 60's in 'n 250 ml PET bruin houer wat toegemaak is met 'n swart kinderdigte deksel, verpak in 'n buite karton.

Bemark deur
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Hierdie voublajet was laas hersien in
TBA

Registrasienommer
RSA: TBA

Toegang tot die ooreenstemmende Professionele Inligting

1182193/00

JUNGLEVITES GUMMY C

PROFESSIONAL INFORMATION

SCHEDULING STATUS
Unscheduled

1. NAME OF THE MEDICINE
JUNGLEVITES GUMMY C
Strength: 100 mg

Pharmaceutical form
Gummy

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each gummy contains:
Ascorbic acid (Vitamin C) 100 mg

Inactive ingredients:
Glucose syrup, sugar, pectin, water, naartjie flavour, beta-carotene colour
Contains sugar: Glucose syrup 0,6 g; Sucrose 1,0 g

3. PHARMACEUTICAL FORM
A translucent orange colour animal-shaped gummy with a fruity scent. Packed in 60's in a 250ml HDPE brown container and closed with brown childproof lid. Packed in an outer carton.

PHARMACOLOGICAL CLASSIFICATION
Category D Complementary Medicine
Discipline 34.11 Health Supplements.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
JUNGLEVITES GUMMY C provides support during high risk times, winter and seasonal changes.
Contributes to the normal function of the immune system.
Vitamin C help reduce the severity and duration of symptoms of cold and flu.
Maintenance of good health.
Contributes to iron absorption from food.
Helps to metabolise fats and proteins.
Contributes to normal collagen formation for the normal function of blood vessels, bones, cartilage, gums, skin and teeth.

4.2 Posology and method of administration
Posology
DOSAGE:
Children 4 years and older:
Take 1 - 2 gummies once daily after food or as recommended by your healthcare practitioner.
Do not exceed the recommended daily dosage without consulting a healthcare practitioner.
Suitable for vegetarians

Method of administration
Orally

4.3 Contraindications
Hypersensitivity (allergy) to any of the ingredients of JUNGLEVITES GUMMY C .

4.4 Special warnings and precautions for use
For patients on any medication or suffering from any medical condition, it is advisable to seek medical advice before starting any new medicine, supplement or remedy.
Recommended dosage(s) should not be exceeded unless on the advice of a healthcare practitioner.
Contains glucose and sucrose, which may have an effect on the glycaemic control of patients with diabetes mellitus.
Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take JUNGLEVITES GUMMY C.
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

4.5 Interaction with other medicines and other forms of interaction

Alkylating agents: interacting rating is moderate, caution should be taken with this combination. Theoretically, antioxidant effects of vitamin C might reduce the effectiveness of alkylating agents

Antitumor antibiotics: interaction rating is moderate and the caution should be taken. Theoretically, the antioxidant effects of vitamin C might reduce the effectiveness of antitumor antibiotics.

Levothyroxine: interaction rating is moderate and caution should be taken. Vitamin C can increase levothyroxine absorption.This suggests that vitamin C increases the oral absorption of levothyroxine, possibly due to a reduction in pH.

Warfarin: interaction rating is moderate, caution should be taken with this combination as, high-dose vitamin C might reduce the levels and effectiveness of warfarin. Tell patients taking warfarin to avoid taking

vitamin C in excessively high doses (greater than 10 grams daily). Lower doses may be safe, but the anticoagulation activity of warfarin should be monitored. Patients who are stabilized on warfarin while taking vitamin C should avoid adjusting vitamin C dosage to prevent the possibility of warfarin resistance.

Interactions with Supplements:
Acerola: Acerola contains high concentrations of vitamin C. Acerola contains an average of 2000 mg of vitamin C per 100 grams of fruit. Concomitant use of acerola with vitamin C supplements might exceed the tolerable upper intake level (UL) of 2000 mg vitamin C per day for adults. This could increase the risk for adverse effects.
Copper: High doses of vitamin C might interfere with copper absorption
Grape: Vitamin C, taken with grape seed polyphenols might increase blood pressure.
Iron: Supplemental and dietary vitamin C can increase the absorption of iron.
Rose hip: Rose hips contain high concentrations of vitamin C.

Interactions with conditions
Alcohol use disorder: Alcohol intake can increase urinary excretion of vitamin C by almost 50%.
Cancer: Cancerous cells accumulate high concentrations of vitamin C. Cancer cells take up the oxidized form of vitamin C, dehydroascorbic acid, then convert it back to vitamin C. However, it is not yet known if supplemental vitamin C benefits the growth of cancer cells or has any detrimental effect on cancer treatments. Until more is known, patients with cancer should only use supplemental vitamin C under the direction of their oncologist.
Chronic kidney disease (CKD): CKD might lead to vitamin C deficiency. Kidney disease can also decrease the excretion of oxalate and increase the risk of oxalate nephropathy. Theoretically, intake of vitamin C supplements might increase the risk of hyperoxaluria in patients with concomitant kidney dysfunction, especially those who have undergone bariatric surgery.

Glucose-6-phosphate dehydrogenase deficiency: Large amounts of vitamin C can cause hemolysis in individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency.
Kidney stones (Nephrolithiasis): Larger amounts of vitamin C can increase the risk of oxalate kidney stones, especially in those prone to oxalate stone formation.
Vitamin C is metabolized to oxalic acid, so increased consumption increases the urinary concentration of oxalic acid and the formation of oxalate kidney stones. People who have a history of oxalate stones seem to be more sensitive to supplemental vitamin C than non-stone formers. Tell patients prone to kidney stone formation to avoid higher doses of vitamin C.

Other interactions
Interactions with Lab Tests
Ascorbinoxidase: Vitamin C can cause false-negative urine results with methods based on hydrolysis and formation of an indophenol blue chromogen.
Aspartate aminotransferase (AST, SGOT): Large amounts of vitamin C can cause falsely elevated results of serum tests relying on color reactions (Redox reactions) and Technicon SMA 12/60.
Biirubin: Large amounts of vitamin C can cause falsely elevated serum test results measured by Technicon SMA 12/60 or colorimetric methods.
Carbamazepine (Tegretol): Large doses of vitamin C can cause a falsely elevated serum assay results measured by Ames ARIS method.
Creatinine: Vitamin C can cause falsely elevated serum creatinine or urine test results.
Glucose: Large amounts of vitamin C can cause false increases in urine test results measured by copper reduction methods (e.g., Clinitest), and false decreases in results measured by glucose oxidase methods (e.g., Clinisix, Tes-Tape) (15). Also, large amounts of vitamin C can cause a falsely elevated blood glucose result when measured using a self-monitoring blood glucose device.
Lactic dehydrogenase (LDH): Vitamin C can cause a false decrease in test results measured by Technicon SMA 12/60 and Abbott 100 methods Occult blood: False-negative guaiac results occur with vitamin C in doses of 250 mg or more daily. Patients should avoid dietary or supplemental vitamin C for 3 days prior to guaiac fecal occult blood testing.
Theophylline: Large amounts of vitamin C can cause a falsely low theophylline serum level when measured by the ARIS system or Ames Seralyzer photometer.
Vitamin B₁₂: Large amounts of vitamin C can interfere with vitamin B₁₂ assay, resulting in falsely low vitamin B₁₂ levels.

4.6 Fertility, pregnancy and lactation
Safe for use during pregnancy and while breastfeeding at the recommended dose.

4.7 Effects on ability to drive and use machines
JUNGLEVITES GUMMY C may not affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects
Orally, vitamin C is well tolerated

Most Common Adverse Effects:
Abdominal cramps, esophagitis, heartburn, headache, osmotic diarrhea, nausea, vomiting. Kidney stones have been reported in those prone to kidney stones. Adverse effects are more likely to occur at doses above the tolerable upper intake level of 2 grams daily.

Serious Adverse Effects (Rare):
There have been rare case reports of carotid inner wall thickening after large doses of vitamin C.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of

the medicine. Health care providers asked to report and suspected adverse reactions to SAHPRA via the "6.4 Adverse Drug Reactions Reporting Form" , found online under SAHPRA's publications https://www.sahpra.org.za/Publications/index/8

4.9 Overdose
Treatment should be symptomatic and supportive. In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.
Higher doses can cause osmotic diarrhea and gastrointestinal upset. Large doses of vitamin C during pregnancy can also cause newborn scurvy, avoing using.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Mechanism of Action:
Vitamin C is an antioxidant for the maintenance of good health.
Helps to metabolise fats and proteins.
Helps in the development and maintenance of bones, cartilage, teeth and gums.
Helps in connective tissue formation.
Helps in wound healing.
Vitamin C might reduce cold symptoms. T-lymphocyte activity, phagocyte function, leukocyte mobility and possibly antibody and interferon production seem to be increased by Vitamin C. Vitamin C might protect normal tissues against reactive oxygen species that are produced by phagocytes during a viral infection.
Beta-carotene contributes to normal growth. Contributes to the maintenance of eyesight, skin, membranes and immune function.

5.2 Pharmacokinetic properties
Absorption and distribution: Vitamin C is well absorbed orally at lower doses, but absorption decreases as the dose increases. Approximately 87% of a 30 mg oral dose is absorbed, 80% of a 100 mg dose is absorbed, 63 % of a 500 mg dose is absorbed, and less than 50% of a 1250 mg dose is absorbed. This is due to the fact that vitamin C is transported from the intestines into the blood by the sodium-dependent vitamin C transporter, which is saturable. The decreased bioavailability of vitamin C with increased dosages, as increased renal excretion, limits the plasma levels attainable with oral vitamin C supplementation.

Excretion: Most vitamin C that is absorbed is excreted in the urine.

5.3 Preclinical safety data
Vitamin C is safe when taken orally in doses below the tolerable upper intake level (UL).When used orally in excessive doses, can significantly increase the risk of adverse effects such as osmotic diarrhea and gastrointestinal upset.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Glucose syrup, sugar, pectin, water, naartjie flavour, beta-carotene colour
Contain sugar(s): Glucose syrup 0,6 g; Sucrose 1,0 g

6.2 Incompatibilities
Unknown

6.3 Shelf life
18 months

6.4 Special precautions for storage
Store at or below 25 °C. KEEP OUT OF REACH OF CHILDREN.
Store away from direct sunlight. Keep it in a dry place.

6.5 Nature and contents of container
A translucent orange colour animal shaped gummy with a fruity scent. Packed in a 250ml PET brown container and closed with black childproof lid. Packed in an outer carton.

6.6. Special precautions for disposal and other handling
None

7. MARKETING BY
Ascendis Consumer Brands (Pty) Ltd
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8. REGISTRATION NUMBER(S)
TBA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
TBA

10. DATE OF REVISION OF THE TEXT
10-02-2025

