

Solution for inhalation

Each 1 mL contains Caffeine anhydrous 10 mg; Lavender oil 0,5 mg; Peppermint oil 0,5 mg; Moringa Seed oil 2,0 mg; White thyme oil 0,5 mg; Camphor oil 0,5 mg; Eucalyptus oil 0,5 mg; Cinnamon Leaf oil 0,5 mg; Pine oil 0,5 mg; Olive oil 1,0 mg; & Menthol 0,5 mg.

1.3.2 Proposed Patient Information Leaflet (PIL)

LINE NO.	CONTENT	REFERENCES
1.	PATIENT INFORMATION LEAFLET	M 1.3.1.1 PI
2.		
3.	SCHEDULING STATUS	
4.	S0	Page 1, line 4
5.		
6.	Respiclear Nebs[®] (solution for inhalation via nebulisation 2,5	Page 1, line 10
7.	mL single dose units)	
8.		
9.	Category D: Complementary Medicine	Page 5, line 98
10.	33.7 Combination Product. <i>This unregistered medicine has not</i>	
11.	<i>been evaluated by the SAHPRA for its quality, safety or</i>	
12.	<i>intended use.</i>	
13.	Read all of this leaflet carefully because it contains	
14.	important information for you	
15.	Respiclear Nebs[®] is available without a doctor's	
16.	prescription, for you to maintain your health.	
17.	Nevertheless, you still need to use Respiclear Nebs[®]	
18.	carefully to get the best results from it.	
19.	<ul style="list-style-type: none"> • Keep this leaflet. You may need to read it again. 	
20.	<ul style="list-style-type: none"> • Do not share Respiclear Nebs[®] with any other person. 	

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21.	<ul style="list-style-type: none"> • Ask your healthcare provider or pharmacist if you need more information or advice. 	
22.		
23.	What is in this leaflet	
24.	1. What Respiclear Nebs® is and what it is used for	
25.	2. What you need to know before you take Respiclear	
26.	Nebs®	
27.	3. How to take Respiclear Nebs®	
28.	4. Possible side effects	
29.	5. How to store Respiclear Nebs®	
30.	6. Contents of the pack and other information	
31.		
32.	1. WHAT RESPICLEAR NEBS® IS AND WHAT IS IT	
33.	USED FOR:	
34.	<i>Category D: human complementary medicine. This medicine</i>	Page 5 lines 98 -
35.	<i>has not been evaluated by the SAHPRA. This medicine is not</i>	106
36.	<i>intended to diagnose, treat, cure or prevent any disease.</i>	s 1-2, lines 19-22
37.	Respiclear Nebs® is a complementary medicine, combination	
38.	product, used to: For symptomatic relief in nasal congestion,	
39.	coryza (head colds) and bronchitis.	
40.	The aromatic vapours of the active compounds have a	
41.	decongestant and anti-inflammatory action on the upper	
42.	respiratory tract, giving symptomatic relief in nasal congestion,	Page 2, lines 25 -
43.	coryza and bronchitis. Humectant properties of saline, together	27
44.	with mucolytic properties of some essential oils may aid the	

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45.	body by providing an alleviating mucolytic effect. Caffeine has	
46.	been shown to act as a bronchodilator and may thus alleviate	
47.	a tight chest in patients suffering from the symptom.	
48.		Page 2, lines 30-
49.	2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE	37, page 3 lines
50.	RESPICLEAR NEBS®:	51-53
51.	<i>Category D: human complementary medicine. This medicine</i>	
52.	<i>has not been evaluated by the SAHPRA. This medicine is not</i>	
53.	<i>intended to diagnose, treat, cure or prevent any disease.</i>	
54.	Do not take Respiclear Nebs®:	
56.	• if you are hypersensitive (allergic) to any of the	
57.	ingredients of Respiclear Nebs® (listed in section 6).	
58.	• If you are pregnant.	
59.	Warnings and precautions:	
60.	RESPICLEAR NEBS® CONTAINS CAFFEINE AND IS	Page 2, line 24
61.	SUGAR FREE.	
62.	Tell your healthcare provide prior to use	
63.	• If you are breastfeeding	
64.	• If you have high blood pressure, glaucoma and/or	
65.	detrusor instability (overactive bladder syndrome).	
66.	Other medicines and RESPICLEAR NEBS®	
67.	Since Respiclear® Nebs are nebulised and inhaled, there is a	Page 3, lines 69-
68.	low probability of medicinal interactions. However, it is advised	77
69.	to contact your doctor or healthcare provider before using	
70.	Respiclear® Nebs as consumption with other medicines which	

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71.	increase blood pressure (e.g. bitter orange extract,	
72.	synephrine, octopamine, ephedra, ephedrine) is not	
73.	recommended. Consumption with lithium or other caffeine-	
74.	containing products (e.g. medications, coffee, tea, colas,	
75.	cocoa, mate) is not recommended.	
76.	RESPICLEAR NEBS® with food, drink and alcohol	Pages 3-4 lines
77.	Consumption with other caffeine-containing products (e.g.	72-77
78.	medications, coffee, tea, colas, cocoa, mate) is not	
79.	recommended.	
80.	Pregnancy and Breastfeeding	Page 4, line 79-80
81.	RESPICLEAR NEBS® should not be used during pregnancy	
82.	and a healthcare provider should be consulted for advice prior	
83.	to taking RESPICLEAR NEBS® when breastfeeding.	
84.	Driving and using machines	Page 3, line 57-58
85.	RESPICLEAR NEBS® has no known effect on an individual's	
86.	ability to drive or operate machinery.	
87.	Taking other medicines with RESPICLEAR NEBS®	
88.	Always tell your healthcare provider if you are taking any other	
89.	medicine.	
90.	3. HOW TO TAKE RESPICLEAR NEBS®:	
91.	<i>Category D: human complementary medicine. This medicine</i>	
92.	<i>has not been evaluated by the SAHPRA. This medicine is not</i>	
93.	<i>intended to diagnose, treat, cure or prevent any disease.</i>	
94.	Don't share medicines prescribed for you with any other	
95.	person. Always take Respiclear® Nebes exactly as described in	

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96.	this leaflet or as your healthcare provider has told you. Check	
97.	with your healthcare provider if you are unsure.	
98.	The usual dose is:	Page 3, lines 47-
99.	Adults and Older Children: Use 2,5 ml to 5 ml (one to two	51
100.	single dose units) of Respiclear® Nebis solution up to four times	
101.	per day.	
102.	Children (4 to 11 years of age): Use 2,5ml (one single dose	
103.	unit) of Respiclear® Nebis solution up to three times per day.	
104.	Method of administration:	Page 3, line 52
105.	Respiclear® Nebis is for inhalation use only, to be breathed in	
106.	through the mouth, using a suitable nebuliser. The solution	
107.	should not be injected or swallowed. Avoid contact with eyes.	
108.	If you take more RESPICLEAR NEBS® than you should: An	
109.	overdose incurred by inhalation is treated by breathing in fresh	
110.	air. Accidental oral intake by mouth may cause diarrhoea,	
111.	stomach-ache, nausea and sweating. In the event of	Page 4, lines 76-
112.	overdosage, consult your doctor or pharmacist. If neither is	77
113.	available, contact the nearest hospital or poison centre.	
114.	If you forget to take a dose of RESPICLEAR NEBS®: Do not	
115.	take a double dose to make up for forgotten individual doses.	
116.		
117.	4. POSSIBLE SIDE EFFECTS	
118.	<i>Category D: human complementary medicine. This medicine</i>	
119.	<i>has not been evaluated by the SAHPRA. This medicine is not</i>	
120.	<i>intended to diagnose, treat, cure or prevent any disease.</i>	

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121.	Respiclear [®] Nebes can have side effects. Possible side effects	Page 4, lines 85-
122.	are nausea, vomiting, increased heart rate, insomnia and	86
123.	headache. If you get side effects, talk to your doctor,	
124.	pharmacist or nurse. If you notice any side effects not	
125.	mentioned in this leaflet, please inform your doctor or	
126.	pharmacist. You can also report side effects to SAHPRA via	
127.	the 6.04 Adverse Drug Reaction Reporting Form”, found	
128.	online under SAHPRA’s publications:	
129.	https://www.sahpra.org.za/Publications/Index/8 . By reporting	
130.	side effects, you can help provide more information on the	
131.	safety of Respiclear [®] Nebes.	
132.		
133.	5. HOW TO STORE RESPICLEAR NEBS[®]	
134.	<i>Category D: human complementary medicine. This medicine</i>	
135.	<i>has not been evaluated by the SAHPRA. This medicine is not</i>	
136.	<i>intended to diagnose, treat, cure or prevent any disease.</i>	
137.	Store all medicines out of reach of children. Store at or below	Page 6 lines 124-
138.	30 °C. Store in the original package / container. Only open a	135
139.	single dose unit immediately before use in a nebuliser. Protect	
140.	from light and moisture. Do not store in a bathroom. Do not use	
141.	after the expiry date stated on the carton. Do not use	
142.	Respiclear [®] Nebes if you notice visible signs of deterioration.	
143.	Return all unused medicine to your pharmacist. Do not dispose	
144.	of unused medicine in drains or sewerage systems (e.g.	
145.	toilets).	

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146.	6. CONTENTS OF THE PACK AND OTHER	
147.	INFORMATION	
148.	<i>Category D: human complementary medicine. This medicine</i>	
149.	<i>has not been evaluated by the SAHPRA. This medicine is not</i>	
150.	<i>intended to diagnose, treat, cure or prevent any disease.</i>	
151.	What Respiclear® Nebes contains:	
152.	Menthol (Mentha arvensis) oil 1,25 mg, Camphor	Pages 1-2, lines
153.	(Cinnamomum camphora) oil 1,25 mg, White thyme (Thymus	16-26
154.	vulgaris) oil 1,25 mg, Eucalyptus (Eucalyptus globulus) oil	
155.	1,25 mg, Cinnamon leaf (Cinnamomum zeylanicum) oil 1,25	
156.	mg, Pine (Pinus sylvestris) oil 1,25 mg, Caffeine Anhydrous	
157.	25 mg, Lavender (Lavandula latifolia) oil 1,25 mg,	
158.	Peppermint (Mentha piperita) oil 1,25 mg, Olive (Olea	
159.	europaea) oil 2,5 mg, Moringa seed (Moringa oleifera) oil 5	
160.	mg. CONTAINS CAFFEINE.	
161.	Excipients with known effect: Saline, Propylene Glycol and	
162.	EDTA2Na (0,1%), RO Water.	
163.		
164.	What Respiclear® Nebes looks like and contents of the	Page 6 lines 129-
165.	pack: Respiclear® Nebes is a clear, oily, aqueous liquid with	133
166.	menthol odour packed in single dose units each containing 2,5	
167.	mL of solution. Each carton contains 3 strips of 5 units (15	
168.	single dose units in total) each marked "Respiclear Nebes" with	
169.	a Patient Information Leaflet.	
170.		

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171.	Holder of Certificate of Registration	Page 6 lines 141-
172.	Microbel Laboratories (Pty) Ltd	144
173.	86 Gazelle Avenue, Corporate Park South	
174.	Midrand, South Africa, 1685	
175.	Email: info@microbel.co.za	
176.	+27 11 076 4000	
177.		
178.	This leaflet was last revised	
179.	20 March 2020	
180.		
181.	Registration/Application number	
182.	TBA by SAHPRA	
183.	Access to the corresponding Professional Information (PI):	
184.	www.obellabs.co.za	

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AFRIKAANS TRANSLATION

LINE NO.	CONTENT	REFERENCES
1.	PASIËNT INLIGTINGS PAMFLET	As per the English
2.		PIL.
3.	SKEDULERING STATUS	
4.	S0	
5.	Respiclear® Nebs (oplossing vir inhalasie via nebulisering in	
6.	'n 2.5 ml enkel-dosis eenheid)	
7.		
8.	KATEGORIE D: komplimentêre medikasie vir menslike	
9.	gebruik	
10.	33.7 Kombinasie produk. Hierdie produk is nog nie deur die	
11.	Medisynebeheerraad (SAPHRA) geëvalueer nie. Hierdie	
12.	produk is nie bedoel vir die diagnose, behandeling, genesing	
13.	of voorkoming van enige siektetoestand nie.	
14.		
15.	Lees hierdie blaadje sorgvuldig vir belangrike inligting	
16.	Hierdie medikasie is sonder 'n doktersvoorskrif beskikbaar vir	
17.	die verligting van 'n geringe toestand. Hierdie medikasie moet	
18.	noukeurig gebruik word vir die beste resultate.	
19.	<ul style="list-style-type: none"> • Bewaar hierdie pamflet, aangesien inligting later dalk 	
20.	<ul style="list-style-type: none"> benodig kan word 	
21.	<ul style="list-style-type: none"> • Moenie hierdie medikasie met enigiemand deel nie 	
22.		

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23.	<ul style="list-style-type: none"> • Raadpleeg u apteker indien u enige inligting of raad 	
24.	benodig	
25.	<ul style="list-style-type: none"> • Raadpleeg 'n dokter indien u toestand vererger, of nie 	
26.	verbeter nie	
27.		
28.	Hierdie blaadjie bevat die volgende inligting:	
29.	1. Wat is Respiclear Nebs [®] en waarvoor word dit gebruik	
30.	2. Wat jy moet weet voordat jy Respiclear Nebs [®] gebruik	
31.	3. Hoe om Respiclear Nebs [®] te neem	
32.	4. Moonlike newe-effekte	
33.	5. Hoe om Respiclear Nebs [®] te bewaar	
34.	6. Inhoud van die houer en ander inligting	
35.		
36.	1. WAT IS RESPICLEAR NEBS[®] WAARVOOR WORD DIT	
37.	GEBRUIK:	
38.	<i>Kategorie D: Menslike komplimentêre medisyne. Hierdie</i>	
39.	<i>medisyne is nog nie deur SAPHRA gevalueer nie . Hierdie</i>	
40.	<i>medikasie is nie bedoel om enige siekte te diagnoseer,</i>	
41.	<i>behandel, genees of voorkom nie.</i>	
42.	Respiclear nebs is 'n kombinasie produk. Die aromatiese	
43.	dampe van die aktiewe verbindings het 'n dekongestiewe en	
44.	anti-inflammatoriese werking op die boonste lugweë wat lei tot	
45.	die simptomatiese verligting van nasale kongestie, verkoue en	
46.	brongitis. Soutoplossing se Humektant-eienskappe, saam met	
47.	die mukolitiese eienskappe van sekere essensiële olies kan	

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48.	bydra om 'n verliggende effek teweeg bring. Kafeïen het	
	brongodilatoriese eienskappe en kan dus help om verligting te	
49.	bied vir 'n stywe bors in pasiënte.	
50.		
51.	2. VOORDAT U RESPICLEAR NEBS® GEBRUIK:	
52.	<i>Kategorie D: Menslike komplimentêre medisyne. Hierdie</i>	
53.	<i>medisyne is nog nie deur SAPHRA gevalueer nie . Hierdie</i>	
54.	medikasie is nie bedoel om enige siekte te diagnoseer,	
56.	behandel, genees of voorkom nie.	
57.	Vermyn indien allergies of hipersensitief vir enige van die	
58.	gelyste bestanddele.	
59.	Moenie gebruik word indien swanger is of borsvoed nie.	
60.	Waarskuwings en spesiale voorsorgmaatreëls	
61.	Respiclear Nebs® bevat kafeïen en is suikervry	
62.	Raadpleeg 'n gesondheidsorgpraktisyn indien u enige	
63.	mediese toestand het.	
64.	Lig jou gesondheidsorgpraktisyn in indien jy:	
65.	<ul style="list-style-type: none"> • Borsvoed 	
66.	<ul style="list-style-type: none"> • Hoe bloeddruk, gloukoom of 'n oor-aktiewe 	
67.	blaassindroom het.	
68.	Respiclear® Nebs en ander medikasie	
69.	Aangesien Respiclear® Nebs genebuliseer word is daar lae	
70.	waarskynlikheid vir enige medisinale interaksies. Pasiënte	
71.	word aangemoedig om eers hul dokter te raadpleeg voor die	
72.	gebruik van Respiclear® Nebs. Die gesamentlike gebruik van	

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73.	litium of ander medisyne (bitter lemoen ekstrak, sinepfrien,	
74.	oktapamien, efedra en efedrien)wat die bloeddruk verhoog,	
75.	word nie aanbeveel nie.	
76.	Respiclear® Nebs en kos en drank	
77.	Gesamentlike gebruik van ander kaffeïen bevattende produkte	
78.	(soos medisyne, koffie, tee, kola, en kakao) word nie	
79.	aanbeveel nie	
80.	Swangerskap en borsvoeding	
81.	Moenie gebruik word indien u swanger is nie en 'n	
82.	gesondheidsorgpraktisyn moed geraadpleeg word voor die	
83.	gebruik tydens borsvoeding.	
84.	Effek op die vermoë om te bestuur en masjinerie te	
85.	gebruik	
86.	Geen effekte op die vermoë om te bestuur of om masjinerie te	
87.	gebruik is aangemeld nie	
88.		
89.	3. HOE OM RESPICLEAR® NEBS TE GEBRUIK :	
90.	<i>Kategorie D: Menslike komplimentêre medisyne. Hierdie</i>	
91.	<i>medisyne is nog nie deur SAPHRA gevalueer nie . Hierdie</i>	
92.	<i>medikasie is nie bedoel om enige siekte te diagnoseer,</i>	
93.	<i>behandel, genees of voorkom nie.</i>	
94.	Moet nie medisyne wat vir jou voorgeskryf is deel met enige	
95.	ander persoon nie. Geburik altyd Respiclear® Nebs soos	
96.	aangedui in hierdie blaadjie of soos voorgeskryf deur jou	
97.	gesondheidsorgpraktisyn.Vra jou dokter indien jy onseker is.	

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98.	<p>Die normale dosis is:</p> <ul style="list-style-type: none"> • Volwassenes en ouer kinders: Gebruik 2,5 ml tot 5 ml (een tot twee enkel dosis eenhede) Respiclear® Nebs oplossing tot en met 4 keer per dag. 	
99.	<ul style="list-style-type: none"> • Kinders (4-11 jaar): gebruik 2.5ml (een enkel eenheid dosis) Respiclear® Nebs oplossing tot en met drie keer 	
100.	per dag.	
101.		
102.	<p>Metode van toediening:</p>	
103.	<p>Respiclear® Nebs is slegs vir inhalasie bedoel, om ingeasem</p>	
104.	te word deur die mond deur van 'n geskikte nebuliseerder	
105.	gebruik te maak. Hierdie oplossing moet nie ingespuut of	
106.	gesluk word nie.	
107.	<p>Indien u meer Respiclear® Nebs geneem het as wat</p>	
108.	<p>aanbeveel is:</p>	
109.	<p>'n Oordosering deur inhalasie kan behandel word deur die</p>	
110.	pasiënt te neem na 'n area waar daar vars lug is. Indien per	
111.	ongeluk oraal ingeneem word kan maagpyn, diarree, naarheid,	
112.	braking en perspirasie voorkom. In die geval van oordosering,	
113.	staak gebruik en raadpleeg u dokter, apteker of ander	
114.	gesondheidsorgpraktisyn. Kontak die naaste hospitaal of	
115.	gifsentrum.	
116.	<p>Indien u vergeet om 'n dosering Respiclear® Nebs te</p>	
117.	<p>neem:</p>	
118.	<p>Moet nie 'n dubbel-dosis neem om op te maak vir dosis wat</p>	
119.	<p>oorgeslaan is nie.</p>	

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120.	4. MOONLTIKE NEWE-EFFEKTE	
121.	<i>Kategorie D: Menslike komplimentêre medisyne. Hierdie</i>	
122.	<i>medisyne is nog nie deur SAPHRA gevalueer nie . Hierdie</i>	
123.	medikasie is nie bedoel om enige siekte te diagnoseer,	
124.	behandel, genees of voorkom nie.	
125.	Moontlike newe-effekte sluit in naarheid, braking, verhoogde	
126.	harttempo insomnie en hoofpyn. Indien jy newe-effekte ervaar	
127.	wat nie in hierdie blaadjie bespreek word nie, kontak jou	
128.	dokter, apteker of verpleegster. Newe-effekte kan ook aan	
129.	SAPHRA gerapporteer word deur die 6.04 “Adverse Drug	
130.	Reactions Reporting Form” te voltooi wat aanlyn beskikbaar is	
131.	by: https:// www.sahpra.org.za/Publications/Index/8 . Deur	
132.	ander newe-effekte te rapporteer kan jy help om meer inligting	
133.	te verskaf rakende die veiligheid van Respiclear® Nebbs.	
134.		
135.	5. BERGINGSAAWYSINGS VIR RESPICLEAR® NEBS:	
136.	<i>Kategorie D: Menslike komplimentêre medisyne. Hierdie</i>	
137.	<i>medisyne is nog nie deur SAPHRA gevalueer nie . Hierdie</i>	
138.	medikasie is nie bedoel om enige siekte te diagnoseer,	
139.	behandel, genees of voorkom nie.	
140.	Bewaar onder 30°C in ‘n koel, droë plek in oorspronklike	
141.	verpakking. Maak slegs een enkel-dosis eenheid oop direk	
142.	voor gebruik in nebuliseerder. Beskerm teen lig en vog. Moet	
143.	nie in ‘n badkamer bewaar nie. Moenie na die vervaldatum	
144.	gebruik nie.	

Solution for inhalation

Each 1 mL contains Caffeine anhydrous 10 mg; Lavender oil 0,5 mg; Peppermint oil 0,5 mg; Moringa Seed oil 2,0 mg; White thyme oil 0,5 mg; Camphor oil 0,5 mg; Eucalyptus oil 0,5 mg; Cinnamon Leaf oil 0,5 mg; Pine oil 0,5 mg; Olive oil 1,0 mg; & Menthol 0,5 mg.

145.	Moet nie gebruik indien daar duidelike veranderinge in die	
146.	produk waargeneem word nie. Neem ongebruikte medisyne	
147.	terug na jou apteker toe. Moenie van ongebruikte medisyne in	
148.	die rioolvervoer of afloop pype ontslae raak nie.	
149.		
150.	6. INHOUD VAN DIE HOUER EN ANDER INLIGTING	
151.	<i>Kategorie D: Menslike komplimentêre medisyne. Hierdie</i>	
152.	<i>medisyne is nog nie deur SAPHRA gevalueer nie . Hierdie</i>	
153.	<i>medikasie is nie bedoel om enige siekte te diagnoseer,</i>	
154.	<i>behandel, genees of voorkom nie.</i>	
155.	Wat Respiclear® Nebes bevat:	
156.	Aktiewe bestanddele: Mentol (Mentha arvensis) olie 1,25 mg,	
157.	Kamfer (Cinnamomum camphora) olie 1,25 mg, Bloekom	
158.	(Eucalyptus globulus) olie 1,25 mg, Kaneelblaar	
159.	(Cinnamomum zeylanicum) olie 1,25 mg, denne (Pinus	
160.	sylvestris) olie 1,25 mg, Anhidriese kaffeïen 25 mg, Laventel	
161.	(Lavandula latifolia) olie 1,25 mg, Peperment (Mentha	
162.	piperita) olie 1,25 mg, Olyf (Olea europaea) olie 2,5 mg,	
163.	Moringa saad (Moringa oleifera) olie 5 mg. Tieme (thymus	
164.	vulgaris) olie 1,25 mg. Bevat kaffeïen	
165.	Onaktiewe bestanddele: Soutwater , Propileen glikool en	
166.	EDTA2Na (0,1%), gesuiwerde water.	
167.		
168.	Hoe Respiclear® Nebes lyk en die inhoud van die houer	
169.	Respiclear® Nebes is 'n deursigtige oliërige water-oplossing met	

Solution for inhalation

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170.	'n mentol geur, verpak in 'n enkel-dosis eenheid wat 2,5 ml	
171.	oplossing bevat. Elke kartonboksie bevat 3 repies van 5	
172.	eenhede elk (totaal van 15 enkel-dosis eenhede) elkeen	
173.	gemerk "Respiclear® Nebbs" met 'n pasiënt inligtingspamflet	
174.		
175.	Houer van registrasie sertifikaat	
176.	Microbel Laboratories (Pty) Ltd	
177.	86 Gazelle Avenue,	
178.	Midrand, Suid-Afrika, 1685	
179.	Epos: info@microbel.co.za	
180.		
181.	Hierdie inligtingspamflet is laaste hersien op	
182.	20 Maart 2020	
183.		
184.	Registrasie nommer	
185.	Hierdie produk is nog nie deur die Medisynebeheerraad	
186.	(SAPHRA) geëvalueer nie. Sal bekend gemaak word deur	
187.	SAPHRA op aanvang van registrasie.	
188.		