

SAHPRA LICENCE NO.		0000000983.-.16		CM REF.	DA02-B2B771	Name of Licence Holder:		Ascendis Pharma (Pty) Ltd							Version:	01-062021
No.	Activity	Name of Medicine	Dosage Form	Pack size per unit - Quantity or Volume	Ingredients and Quantities		Dosage	Registration or Application No.	Sub-Category	Class or Discipline	Route of Administration	Risk	Intended Use	Storage Conditions		
1	Manufactured (including import and export)	Flumune C Immune Booster	Tablet - Effervescent	20s	Each effervescent tablet contains: Echinacea purpurea (L.) Moench (Echinacea)12,5 mg [tops, 4:1 extract, providing 50 mg dried herb equivalent] Ascorbic acid (Vitamin C)1000 mg Zinc citrate dihydrate 32,25 mg providing elemental zinc 10 mg Cholecalciferol (Vitamin D3)400 IU		Adults and children over 12 years: 1 tablet daily dissolved in a full glass of water.	To be allocated at time of submission / registration.	Discipline specific	Combination product	Oral	Low	Flumune C Immune Booster is specifically formulated to help support, enhance, improve and promote the immune system.	At or below 25 ° C		
2	Manufactured (including import and export)	Flumune Intensive Softgels	Capsule - Soft	20s	Each capsule contains: Sambucus nigra L. (Elderberry)82,5 mg [fruit, 20:1 extract, providing 1650 mg dried herb equivalent] Echinacea purpurea (L.) Moench (Echinacea)56,25 mg [tops, 4:1 extract, providing 225 mg dried herb equivalent] Pelargonium sidoides DC. (Black geranium)22,5 mg [root, 6,25:1 extract, providing 140,63 mg dried herb equivalent] Zinc gluconate38,2 mg providing elemental zinc 5 mg Cholecalciferol (Vitamin D3)100 IU		Children aged 5-11: 1 capsule twice daily. Adults and children 12 years and older: 2 capsules twice daily.	To be allocated at time of submission / registration.	Discipline specific	Combination product	Oral	Low	Flumune Intensive Softgels helps with the relief of symptoms associated with colds and flu, such as nasal congestion, chest congestion, cough and runny nose.	At or below 25 ° C		
3	Manufactured (including import and export)	Flumune Intensive Capsule	Capsule - Hard	20s	Each capsule contains: Sambucus nigra L. (Elderberry)82,5 mg [fruit, 20:1 extract, providing 1650 mg dried herb equivalent] Echinacea purpurea (L.) Moench (Echinacea)56,25 mg [tops, 4:1 extract, providing 225 mg dried herb equivalent] Pelargonium sidoides DC. (Black geranium)22,5 mg [root, 6,25:1 extract, providing 140,63 mg dried herb equivalent] Zinc gluconate38,2 mg providing elemental zinc 5 mg Cholecalciferol (Vitamin D3)100 IU		Children aged 5-11: 1 capsule twice daily. Adults and children 12 years and older: 2 capsules twice daily.	To be allocated at time of submission / registration.	Discipline specific	Combination product	Oral	Low	Flumune Intensive Capsules helps with the relief of symptoms associated with colds and flu, such as nasal congestion, chest congestion, cough and runny nose	At or below 25 ° C		
4	Manufactured (including import and export)	Flumune Intensive Cough Syrup	Liquid	100 ml	Each 5 mL contains: Sambucus nigra L. (Elderberry)55 mg [fruit, 20:1 extract, providing 1100 mg dried herb equivalent] Hedera helix L. (English Ivy)17,5 mg [Leaf, 6,5:1 extract, providing 113,75 mg dried herb equivalent] Pelargonium sidoides DC. (Black geranium)15 mg [root, 6,25:1 extract, providing 93,75 mg dried herb equivalent]		Children aged 3-5 years of age- 2,5 mL three times daily Children aged 6-11 years of age- 2,5-5 mL three times daily Children over 12 years of age- 7,5 mL three times daily Adults (>18 years of age)- 10 mL three times daily	To be allocated at time of submission / registration.	Discipline specific	Western Herbal Medicine	Oral	Low	Flumune Intensive Cough Syrup helps maintain and support lung and immune health. Flumune Cough Syrup may also be used as a mucolytic expectorant to help thin mucous and relieve a productive cough as well as reducing the frequency and intensity of a cough. Helps to relieve lung congestion.	At or below 25 ° C		
5	Manufactured (including import and export)	Flumune Intensive Cough Syrup	Liquid	200 ml	Each 5 mL contains: Sambucus nigra L. (Elderberry)55 mg [fruit, 20:1 extract, providing 1100 mg dried herb equivalent] Hedera helix L. (English Ivy)17,5 mg [leaf, 6,5:1 extract, providing 113,75 mg dried herb equivalent] Pelargonium sidoides DC. (Black geranium)15 mg [root, 6,25:1 extract, providing 93,75 mg dried herb equivalent]		Children aged 3-5 years of age- 2,5 mL three times daily Children aged 6-11 years of age- 2,5-5 mL three times daily Children over 12 years of age- 7,5 mL three times daily Adults (>18 years of age)- 10 mL three times daily	To be allocated at time of submission / registration.	Discipline specific	Western Herbal Medicine	Oral	Low	Flumune Intensive Cough Syrup helps maintain and support lung and immune health. Flumune Cough Syrup may also be used as a mucolytic expectorant to help thin mucous and relieve a productive cough as well as reducing the frequency and intensity of a cough. Helps to relieve lung congestion.	At or below 25 ° C		
6	Manufactured (including import and export)	Flumune Paediatric Cough Syrup	Liquid	100 ml	Each 1 mL contains: Hedera helix L. (English Ivy)17,5 mg [leaf, 6,5:1 extract, providing 113, 75 mg dried herb equivalent]		Infants: 0-1 year and children 1-5 years- 2,5 mL three times daily. Children: 6-9 years and adolescents older than 10 years- 5 mL three times daily. Adults: 5-7,5 mL three times daily.	To be allocated at time of submission / registration.	Discipline specific	Western Herbal Medicine	Oral	Low	Flumune Paediatric Cough Syrup helps maintain and support lung health. Flumune Paediatric Cough Syrup may also be used as a mucolytic expectorant to help thin mucous and relieve a productive cough as well as reducing the frequency and intensity of a cough. Helps to relieve lung congestion.	At or below 25 ° C		
7	Manufactured (including import and export)	Flumune C Intensive Effervescent	Tablet - Effervescent	12s	Each effervescent tablet contains: Echinacea purpurea (L.) Moench (Echinacea)75 mg [tops, 4:1 extract, providing 300 mg dried herb equivalent] Pelargonium sidoides DC. (Black geranium)30 mg [root, 6,25:1 extract, providing 187,5 mg dried herb equivalent] Sambucus nigra L. (Elderberry)21,67 mg [fruit, 20:1 extract, providing 433,4 mg dried herb equivalent] Ascorbic acid (Vitamin C)333,3 mg Zinc gluconate38,2 mg providing elemental zinc 5 mg		Adults and children 12 years and older: Take 1 effervescent tablet, dissolved in half a glass of water, three times a day, after a meal.	To be allocated at time of submission / registration.	Discipline specific	Combination product	Oral	Low	Flumune C Intensive effervescent helps with the relieve of symptoms associated with colds and flu, such as nasal congestion, chest congestion, cough and runny nose. Antioxidant support for the maintenance and enhancement of good health.	At or below 25 ° C		