

1.3.2 Approved Patient Information Leaflet

1 SCHEDULING STATUS

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3 PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

4 DURO-TUSS LINCTUS

5 Salbutamol Sulphate 2,41 mg and Bromhexine Hydrochloride 4 mg per 5 ml liquid

6 Read all of this leaflet carefully because it contains important information for you

7 **DURO-TUSS LINCTUS** is available without a doctor's prescription, for you to treat a mild illness.

8 Nevertheless you still need to use **DURO-TUSS LINCTUS** carefully to get the best results from it.

- 9
- Keep this leaflet. You may need to read it again.
- 10
- Do not share **DURO-TUSS LINCTUS** with any other person.
- 11
- Ask your pharmacist if you need more information or advice.
- 12
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

13 WHAT DURO-TUSS LINCTUS CONTAINS

- 14
- The active ingredients are salbutamol sulphate 2,41 mg and bromhexine hydrochloride 4 mg per
- 15 5 ml.
- 16
- The other ingredients are citric acid, hydroxyethylcellulose, menthol, orange flavour, sodium
- 17 benzoate, sucralose, propylene glycol and purified water.

18 **DURO-TUSS LINCTUS** contains no sugar or alcohol.

19 WHAT DURO-TUSS LINCTUS IS USED FOR

20 **DURO-TUSS LINCTUS** is indicated for the relief of cough associated with bronchospasm (wheezing).

21 BEFORE YOU TAKE DURO-TUSS LINCTUS

22 **Do not take DURO-TUSS LINCTUS:**

23 • if you are hypersensitive (allergic) to salbutamol, bromhexine or any of the other ingredients of

24 **DURO-TUSS LINCTUS**

25 • if your heart beats irregularly (cardiac dysrhythmias) or too fast (tachycardia)

26 • if you are receiving monoamine oxidase inhibitors (MAOI's) or within 14 days of stopping
27 treatment with MAOI's (medicines for treatment of depression).

28 **Take special care with DURO-TUSS LINCTUS:**

29 **Tell your doctor if you suffer from the following:**

30 • hyperthyroidism (over activity of the thyroid gland)

31 • myocardial insufficiency (malfunction of the heart muscle)

32 • dysrhythmias (irregular heartbeat)

33 • susceptibility to prolongation of the QT-interval (the time between the start of the Q wave and
34 the end of the T wave in the heart's electrical cycle)

35 • hypertension (high blood pressure)

36 • history of peptic ulcer

37 • diabetes mellitus

38 • asthma (the doctor may need to monitor the potassium levels in your blood)

39 • if you have a history of peptic ulceration

40 • severe hepatic (liver) or renal (kidney) impairment.

41 High doses may increase the risk of serious side effects, including irregular heartbeat (cardiac
42 dysrhythmias). Do not take more than the recommended dose. (See **HOW TO TAKE DURO-TUSS**
43 **LINCTUS**).

44 **Pregnancy and Breastfeeding:**

45 You should not take **DURO-TUSS LINCTUS** if you are pregnant or breastfeeding.

46 The safety of **DURO-TUSS LINCTUS** in pregnancy and breastfeeding has not been established.

47 **DURO-TUSS LINCTUS** may delay onset of labour.

48 If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other
49 healthcare professional for advice before taking this medicine.

50 **Taking other medicines with DURO-TUSS LINCTUS:**

51 Always tell your healthcare professional if you are taking any other medicine. (This includes
52 complementary or traditional medicines).

53 If you are taking other medicines on a regular basis, including complementary or traditional medicines,
54 the use of **DURO-TUSS LINCTUS** with these medicines may cause undesirable interactions. Please
55 consult your doctor, pharmacist or other healthcare professional, for advice.

56 Do not take **DURO-TUSS LINCTUS** if you are taking diuretics (water tablets), corticosteroids or
57 xanthines.

58 **HOW TO TAKE DURO-TUSS LINCTUS**

59 Do not share medicines prescribed for you with any other person.

60 Always take **DURO-TUSS LINCTUS** exactly as your doctor has instructed you. You should check
61 with your doctor or pharmacist if you are unsure. The usual dose is:

62 **Adults:** 10 ml (two medicine measures) three to four times a day

63 **Children 6 – 12 years:** 5 ml (one medicine measure) three to four times a day

64 **Children 2 – 6 years:** 2,5 ml – 5 ml (half to one medicine measure) three to four times a day.

65 Do not exceed the recommended dose.

66 **DURO-TUSS LINCTUS** is suitable for children, elderly and diabetics.

67 If you have the impression that the effect of **DURO-TUSS LINCTUS** is too strong or too weak for you,
68 tell your doctor or pharmacist.

69 **If you take more DURO-TUSS LINCTUS than you should:**

70 Some of the following may be experienced in case of an overdose:

71 Tachycardia (fast heart rate)

72 Tremor

73 Hyperglycaemia (high blood sugar)

74 In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the
75 nearest hospital or poison control center.

76 **If you forget to take DURO-TUSS LINCTUS:**

77 Do not take a double dose to make up for a forgotten individual dose.

78 **POSSIBLE SIDE EFFECTS**

79 **DURO-TUSS LINCTUS** can have side effects:

80 Not all side effects reported for **DURO-TUSS LINCTUS** are included in this leaflet. Should your
81 general health worsen while taking this medicine, please consult your doctor, pharmacist or other
82 healthcare professional for advice.

83 If any of the following happens, stop taking **DURO-TUSS LINCTUS** and tell your doctor immediately
84 or go to the casualty department at your nearest hospital:

- 85 • hypersensitivity (allergic) reactions
- 86 • difficulty breathing after using an inhalant (paradoxical bronchospasm)
- 87 • swelling (angioedema)
- 88 • hives (urticaria)
- 89 • low blood pressure (hypotension)
- 90 • fainting (collapse).

91 These are all very serious side effects. If you have them, you may have had a serious allergic reaction
92 to **DURO-TUSS LINCTUS**. You may need urgent medical attention or hospitalisation.

93 Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice
94 any of the following:

- 95 • high blood sugar
- 96 • low levels of potassium in the blood
- 97 • if your heart beats too fast
- 98 • strong, irregular heartbeat
- 99 • reduced blood flow to your heart
- 100 • flushing
- 101 • a rise in certain liver enzymes.

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

103 The following side effects were reported (frequency unknown), tell your doctor if you notice any of the
104 following:

- 105 • hallucinations in children
- 106 • hyperactivity and restlessness
- 107 • fine tremor of muscles, particularly the hands
- 108 • cramps
- 109 • headache
- 110 • nervous tension
- 111 • gastrointestinal side effects
- 112 • skin rashes
- 113 • dizziness
- 114 • sweating.

115 If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

116 **STORING AND DISPOSING OF DURO-TUSS LINCTUS**

117 Store at or below 30 °C.

118 Protect from light.

119 Keep all medicines out of the reach and sight of children.

120 Do not use after the expiry date stated on the label and carton.

121 Return all unused medicine to your pharmacist.

122 Do not dispose of unused medicine in drains or sewerage systems (eg toilets).

123 **PRESENTATION OF DURO-TUSS LINCTUS**

124 Amber plastic (PET) bottles containing 100 ml and 200 ml. The bottles are packed in a printed unit
125 carton.

126 **IDENTIFICATION OF DURO-TUSS LINCTUS**

127 A clear, colourless, slightly viscous liquid with an odour of orange.

128 **REGISTRATION NUMBER**

129 A39/10.1/0390

130 **NAME AND ADDRESS OF REGISTRATION HOLDER**

131 iNova Pharmaceuticals (Pty) Ltd

132 15e Riley Road

133 Bedfordview

134 South Africa

135 **DATE OF PUBLICATION**

136 Date of registration: 10 August 2007

137 Date of latest revision: 23 November 2017