PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

DURO-TUSS LINCTUS, 2,41 milligram, 4 milligrams per 5 millilitres, Liquid

Salbutamol Sulphate, Bromhexine Hydrochloride

SUGAR FREE

Contains sweetener (sucralose 2,5 mg /5 ml)

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DURO-TUSS LINCTUS 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 after 10 days.

What is in this leaflet

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

1. What DURO-TUSS LINCTUS is and what it is used for

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

2. What you need to know before you take DURO-TUSS LINCTUS

Do not take DURO-TUSS LINCTUS:

- if you are hypersensitive (allergic) to salbutamol, bromhexine or any of the other ingredients of DURO-TUSS LINCTUS (listed in section 6)
- if your heart beats irregularly (cardiac dysrhythmias) or too fast (tachycardia)
- if you are receiving monoamine oxidase inhibitors (MAOI's) or within 14 days of stopping treatment with MAOI's (medicines for treatment of depression).

Warnings and precautions

Take special care with DURO-TUSS LINCTUS:

Tell your doctor if you suffer from the following:

- hyperthyroidism (over activity of the thyroid gland)
- myocardial insufficiency (malfunction of the heart muscle)
- dysrhythmias (irregular heartbeat)
- susceptibility to prolongation of the QT-interval (the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle)
- history of shortness of breath or chest pain
- hypertension (high blood pressure)
- history of peptic ulcer
- diabetes mellitus
- asthma (the doctor may need to monitor the potassium levels in your blood)
- if you have a history of peptic ulceration
- severe hepatic (liver) or renal (kidney) impairment
- a severe skin reaction that may occur.

High doses may increase the risk of serious side effects, including irregular heartbeat (cardiac dysrhythmias). Do not take more than the recommended dose. (See How to take DURO-TUSS LINCTUS).

Other medicines and DURO-TUSS LINCTUS

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

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

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

Do not take DURO-TUSS LINCTUS if you are taking propranolol.

Do not take DURO-TUSS LINCTUS if you are taking non-steroidal anti-inflammatory drugs (e.g. diclofenac, ibuprofen, salicylates) can cause a mutual intensification of the gastric mucosal irritant effects.

Be cautious to take DURO-TUSS LINCTUS and certain antibiotics (e,g. erythromycin) together.

DURO-TUSS LINCTUS and certain antibiotics, amoxicillin, erythromycin and oxytetracycline should not be taken together as the concentrations in the sputum and bronchial secretions can be increased.

Pregnancy and breastfeeding

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

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

DURO-TUSS LINCTUS may delay onset of labour.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

None known.

3. How to take DURO-TUSS LINCTUS

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

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

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

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

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

Do not exceed the recommended dose.

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

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

If you take more DURO-TUSS LINCTUS than you should

Some of the following may be experienced in case of an overdosage:

Tachycardia (fast heart rate)

Tremor

Hyperglycaemia (high blood sugar)

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 DURO-TUSS LINCTUS

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

4. Possible side effects

DURO-TUSS LINCTUS can have side effects:

Not all side effects reported for DURO-TUSS LINCTUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DURO-TUSS LINCTUS, please consult your healthcare provider for advice.

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

- hypersensitivity (allergic) reactions
- difficulty breathing after using an inhalant (paradoxical bronchospasm)
- swelling (angioedema)
- hives (urticaria)
- low blood pressure (hypotension)
- fainting (collapse).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DURO-TUSS LINCTUS. 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:

- high blood sugar
- low levels of potassium in the blood
- if your heart beats too fast
- strong, irregular heartbeat
- reduced blood flow to your heart

- flushing
- a rise in certain liver enzymes.

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:

- headache
- fine tremor of muscles, particularly the hands
- nervous tension
- muscle cramps.

Less Frequent side effects:

- upper stomach pain, nausea, vomiting, diarrhoea
- hyperactivity and restlessness
- skin rashes
- dizziness.

Side effects with unknown frequency:

- hallucinations in children
- heart attack
- sweating.

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 nurse. You can also report side effects to SAHPRA' publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DURO-TUSS LINCTUS.

5. How to store DURO-TUSS LINCTUS

Store at or below 30 °C.

Protect from light.

Store all medicines out of reach of children.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What DURO-TUSS LINCTUS contains

The active ingredients are salbutamol sulphate 2,41 mg and bromhexine hydrochloride 4 mg per 5 ml.

The other ingredients are citric acid, hydroxyethylcellulose, menthol, orange flavour, sodium benzoate, sucralose, propylene glycol and purified water.

What DURO-TUSS LINCTUS looks like and contents of the pack

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

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

Holder of Certificate of Registration

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