Duro-Tuss® Linctus

Package Insert

SCHEDULING STATUS
S2

PROPRIETARY NAME AND DOSAGE FORM
DURO-TUSS LINCTUS (Liquid)

COMPOSITION
Each 5 mℓ liquid contains: Salbutamol sulphate 2,41 mg
Bromhexine hydrochloride 4 mg
Contains sweetener: Sucralose 2,5 mg/5 mℓ
Preservative: Sodium Benzoate 0,2 % *m/v*
Other inactive ingredients are citric acid anhydrous, hydroxyethylcellulose, menthol, orange flavour, propylene glycol and purified water.
Contains no sugar or alcohol.

PHARMACOLOGICAL CLASSIFICATION
A.10.1 Antitussives and expectorants.

PHARMACOLOGICAL ACTION
Salbutamol sulphate
Pharmacodynamic properties
Salbutamol is a β_2-selective adrenergic bronchodilator. It acts by stimulating β_2-adrenergic receptors in the lungs to relax bronchial smooth muscle.
The onset of action is within 30 minutes, with a peak effect between 2 to 3 hours after the dose, and a duration of action of up to 6 hours.
Pharmacokinetic properties
Salbutamol is readily absorbed from the gastrointestinal tract. It is subject to first pass metabolism in the liver and possibly in the gut wall. The main metabolite is an inactive sulfate conjugate. It is excreted in the urine as metabolites and unchanged salbutamol, and some is excreted in the faeces. The plasma half-life of Salbutamol has been estimated to range from 4 to 6 hours.
Bromhexine hydrochloride
Pharmacodynamic properties
Bromhexine hydrochloride reduces the viscosity of non-infected secretions from mucous cells in the respiratory tract, in vitro.
Pharmacokinetic properties
Bromhexine hydrochloride is well absorbed from the gastrointestinal tract with peak plasma concentrations after about 1 hour. Bromhexine undergoes extensive first-pass metabolism in the liver, with a bioavailability of 20 %. It is widely distributed to body tissues. About 85 % to 90 % of a dose is excreted in the urine mainly as metabolites, including ambroxol. Bromhexine is highly bound to plasma proteins. It has a terminal elimination half-life of 13 to 40 hours. Bromhexine crosses the blood-brain barrier and small amounts cross the placenta.

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

CONTRAINDICATIONS
DURO-TUSS LINCTUS is contraindicated in:
- Patients with known hypersensitivity to salbutamol, bromhexine or to any other ingredients in **DURO-TUSS LINCTUS**.
- Patients with cardiac dysrhythmias or tachycardia.
- Patients receiving monoamine oxidase inhibitors (MAOI's) or within 14 days of MAOI's termination.

WARNINGS AND SPECIAL PRECAUTIONS
Salbutamol Sulphate
Use with caution in hyperthyroidism, myocardial insufficiency, susceptibility to QT-interval prolongation, hypertension, diabetes mellitus, and in severe asthma.
Plasma-potassium concentrations should be monitored in severe asthma as hypokalaemia may occur. The risk can be potentiated by hypoxia and acidosis, or the concomitant use with other medicines that cause hypokalaemia or cardiac dysrhythmias. (See **INTERACTIONS** and **SIDE EFFECTS.**)
High doses may increase the risk of serious side effects, including cardiac dysrhythmias, the maximum dose should not be exceeded.
Bromhexine hydrochloride
Use with care in patients with a history of peptic ulceration.
Care is also advisable in asthmatic patients.
Clearance of bromhexine or its metabolites may be reduced in patients with severe hepatic or renal impairment.

INTERACTIONS
Salbutamol Sulphate
Concomitant administration of **DURO-TUSS LINCTUS** with sympathomimetics, diuretics, corticosteroids or xanthines e.g. theophylline, increases the risk of hypokalaemia. (See **WARNINGS AND SPECIAL PRECAUTIONS.**)

PREGNANCY AND LACTATION
The safety of **DURO-TUSS LINCTUS** in pregnancy and lactating women has not been established.
DURO-TUSS LINCTUS may delay onset of labour.
Small amounts of bromhexine cross the placenta.

DOSAGE AND DIRECTIONS FOR USE
Adults: 10 mℓ three to four times a day
Children 6 – 12 years: 5 mℓ three to four times a day
Children 2 – 6 years: 2,5 mℓ – 5 mℓ three to four times a day
Do not exceed the recommended dose.
Suitable for children, elderly and diabetics.

SIDE EFFECTS
The following side effects have been reported:
Salbutamol sulphate
Immune system disorders
Frequency unknown: Hypersensitivity reactions, including paradoxical bronchospasm, angioedema, urticaria, hypotension, and collapse.
Metabolism and nutrition disorders
Frequency unknown: Hyperglycaemia. Lactic acidosis. Hypokalaemia that may be potentiated by concomitant therapy with corticosteroids, diuretics, or xanthines and by hypoxia and acidosis. (See **WARNINGS AND SPECIAL PRECAUTIONS.**)
Nervous system disorders
Frequency unknown: Hallucinations in children, hyperactivity and restlessness.
Cardiac disorders
Frequency unknown: Tachycardia due to increased sympathetic effects on the cardiovascular system, palpitations. Myocardial ischaemia.
Vascular disorders
Frequency unknown: Peripheral vasodilation with flushing, hypotension.
Musculoskeletal, connective tissue and bone disorders
Frequency unknown: Fine tremor of skeletal muscle particularly the hands.
Less frequent: Cramps.
General disorders and administrative site conditions
Frequency unknown: Headache and nervous tension.
Bromhexine Hydrochloride
Gastrointestinal disorders
Less frequent: Gastrointestinal side effects.
Hepato-biliary disorders
Frequency unknown: Transient rise in serum aminotransferase values.
Skin and subcutaneous tissue disorders
Frequency unknown: Skin rashes.
General disorders and administrative site conditions
Frequency unknown: Headache, dizziness, sweating.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See **SIDE EFFECTS**. Salbutamol overdosage may result in tachycardia, central nervous system stimulation, tremor, hypokalaemia, hyperglycaemia and lactic acidosis. Treatment is symptomatic and supportive.
Activated charcoal may be considered in patients who present within 1 hour of overdosage.

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

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

STORAGE INSTRUCTIONS
Store at or below 30 °C. Protect from light. Shake bottle before use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
A39/10.1/0390

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
iNova Pharmaceuticals (Pty) Ltd
15E Riley Road, Bedfordview, 2007

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Duro-Tuss® Linctus

Patient information leaflet

SCHEDULING STATUS
S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
DURO-TUSS LINCTUS
Salbutamol Sulphate 2,41 mg and Bromhexine Hydrochloride 4 mg per 5 mℓ liquid
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 DURO-TUSS LINCTUS CONTAINS
- The active ingredients are:
  salbutamol sulphate 2,41 mg and bromhexine hydrochloride 4 mg per 5 mℓ.
  DURO-TUSS LINCTUS contains sweetener (sucralose 2,5 mg/5 mℓ).
- The other ingredients are citric acid, hydroxyethylcellulose, menthol, orange flavour, sodium benzoate, propylene glycol and purified water.

DURO-TUSS LINCTUS contains no sugar or alcohol.

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

BEFORE YOU TAKE DURO-TUSS LINCTUS
Do not take DURO-TUSS LINCTUS:
- if you are hypersensitive (allergic) to salbutamol sulphate, bromhexine hydrochloride or any of the other ingredients of **DURO-TUSS LINCTUS**.
- 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).

Take special care with DURO-TUSS LINCTUS:
Tell your doctor if you are suffering 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)
- hypertension (high blood pressure)
- history of peptic ulcer
- diabetes mellitus
- asthma (the doctor may need to monitor the potassium levels in your blood)
- severe hepatic (liver) or renal (kidney) impairment.

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**).
Pregnancy and Breastfeeding:
You should not take **DURO-TUSS LINCTUS** if you are pregnant or breast feeding.
The safety of **DURO-TUSS LINCTUS** in pregnancy and lactating women has not been established.
DURO-TUSS LINCTUS may delay onset of labour.
If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.
Taking other medicines with DURO-TUSS LINCTUS:
Always tell your healthcare professional if you are taking any other medicine. (This includes 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 professional, for advice.
Do not take **DURO-TUSS LINCTUS** if you are taking diuretics (water tablets), corticosteroids or xanthines.

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)
- Build-up of lactate in the body (lactic acidosis)

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.
If you forget to take DURO-TUSS LINCTUS:
Do not take a double dose to make up for a forgotten individual dose.

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 while taking this medicine, please consult your doctor, pharmacist or other health care professional 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)
- build-up of lactate in the body (lactic acidosis).

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.
The following side effects were reported (frequency unknown), tell your doctor if you notice any of the following:
- hallucinations in children
- hyperactivity and restlessness
- fine tremor of muscles particularly the hands
- cramps
- headache
- nervous tension
- gastrointestinal side effects
- dizziness
- sweating
- skin rash

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

STORING AND DISPOSING OF DURO-TUSS LINCTUS
Store at or below 30 °C.
Protect from light. Shake bottle before use.
Keep all medicines out of the reach and sight 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).

PRESENTATION OF DURO-TUSS LINCTUS
Amber plastic (PET) bottles containing 100 mℓ and 200 mℓ. The bottles are packed in a printed unit carton.

IDENTIFICATION OF DURO-TUSS LINCTUS
A clear, colourless, slightly viscous liquid with an odour of orange.

REGISTRATION NUMBER
A39/10.1/0390

NAME AND ADDRESS OF REGISTRATION HOLDER
iNova Pharmaceuticals (Pty) Ltd
15E Riley Road, Bedfordview, 2007

DATE OF PUBLICATION
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Duro-Tuss® Linctus

Voubiljet

SKEDULERINGSTATUS
S2
EIENDOMSNAAM EN DOSEERVORM
DURO-TUSS LINCTUS (Vloeistof)

SAMESTELLING
Elke 5 mℓ vloeistof bevat: Salbutamolsulfaat 2,41 mg
Bromheksienhidrochloried 4 mg
Bevat versoeter: Sukralose 2,5/5 mℓ
Preserveermiddel: Natriumbensoaat 0,2 % *m/v*
Die ander onaktiewe bestanddele is anhidriese sitroensuur, hidroksie-etielsellulose, menthol, lemoengeur, propileenglikol en gesuiwerde water.
Bevat geen suiker of alkohol nie.
FARMAKOLOGIESE KLASSIFIKASIE
A.10.1 Hoesmiddels en ekspektorante.
FARMAKOLOGIESE WERKING
Salbutamolsulfaat
Farmakodinamika
Salbutamol is 'n β_2-selektiewe adrenergiese brongodilator. Dit werk deur β_2-adrenergiese reseptore in die longe te stimuleer om die brongiale gladdespier te ontspan.
Die aanvang van werking is binne 30 minute, met 'n piek effek tussen 2 tot 3 uur na die dosis geneem is, en met 'n werksduur van tot 6 uur.
Farmakokinetika
Salbutamol word geredelik uit die spysverteringskanaal geabsorbeer. Dit ondergaan eerstedeurgangmetabolisme in die lewer en moontlik in die maagwand. Die belangrikste metaboliet is 'n onaktiewe sulfaatkonjugaat. Dit word as metaboliete en onveranderde salbutamol in die uriene en 'n gedeelte in die feses uitgeskei. Die plasmahalfleeftyd van salbutamol wissel na raming tussen 4 en 6 uur.
Bromheksien hidrochloried
Farmakodinamika
Bromheksien hidrochloried verlaag die viskositeit van die onbesmette afskeidings van slymselle in die asemhalingsweg in vitro.
Farmakokinetika
Bromheksienhidrochloried word goed na ongeveer 1 uur uit die spysverteringskanaal geabsorbeer en ondergaan grootskaalse eerstedeurgangmetabolisme in die lewer met 'n uiteindelike biobeskikbaarheid van 20 %. Dit word wyd versprei na liggaamsweefsel. Ongeveer 85 % tot 90 % van 'n dosis word hoofsaaklik as metaboliete in die uriene uitgeskei, insluitend ambroksol. Bromheksie n is tot 'n groot mate aan plasmaproteïene gebind. Dit het 'n terminale eliminasiehalfleeftyd van 13 tot 40 uur. Broomheksien kruis die bloedbreinskans en slegs 'n klein hoeveelheid kruis die plasenta.
INDIKASIES
DURO-TUSS LINCTUS is aangedui vir die verligting van hoes wat gepaard gaan met brongospasma (aamborstigheid).
KONTRAINDIKASIES
DURO-TUSS LINCTUS is teenaangedui in:
- Pasiënte met bekende hipersensitiwiteit teenoor salbutamol, broomheksien of enige van die ander bestanddele in **DURO-TUSS LINCTUS**.
- Pasiënte met hartdisritmie of tagikardie.
- Pasiënte wat monoamienoksidaseremmers (MAOR's) gebruik en ook nie binne 14 dae na behandeling daarmee gestaak is nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Salbutamolsulfaat
Gebruik met sorg in gevalle van hipertiroïedisme, swak hartfunksie, vatbaarheid vir verlenging van die QT-interval, hipertensie, diabetes mellitus en ernstige asma.
Plasma-kalium konsentrasies moet gemonitor word in erge asma gevalle aangesien hipokalemie kan voorkom. Die risiko kan vererger word deur hipoksie en asidose, of die gepaardgaande gebruik met ander medisyne wat hipokalemie of hartdisritmie veroorsaak. (sien **INTERAKSIES** en **NEWE- EFFEKTE**)
Hoë dosisse kan die risiko van ernstige newe-effekte verhoog, insluitend kardiale disritmie, die maksimum dosis moet nie oorskry word nie.
Bromheksienhidrochloried
Gebruik met sorg in pasiënte met 'n geskiedenis van peptiese ulserasie.
Sorg is ook raadsaam by asmatiese pasiënte.
Die uitskeiding van bromheksien of sy metaboliete kan verminder word in pasiënte met ernstige lewer- of nierinkorting.
INTERAKSIES
Salbutamolsulfaat
Gelyktydige toediening van **DURO-TUSS LINCTUS** met simpatomimetika, diuretika, kortikosteroïede of xantiene bv. teofillien, verhoog die risiko van hipokalemie. (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).

SWANGERSKAP EN BORSVOEDING
Die veilige gebruik van **DURO-TUSS LINCTUS** gedurende swangerskap en in borsvoedende vroue is nog nie vasgestel nie.
DURO-TUSS LINCTUS mag die aanvang van kraam vertraag.
Klein hoeveelhede bromheksien kruis die plasenta.
DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes: 10 mℓ drie tot vier maal per dag
Kinders 6 – 12 jaar: 5 mℓ drie tot vier maal per dag
Kinders 2 – 6 jaar: 2,5 mℓ – 5 mℓ drie tot vier maal per dag
Die aanbevole dosis moet nie oorskry word nie.
Geskik vir kinders, bejaarde en diabetiese pasiënte.
NEWE-EFFEKTE
Die volgende newe-effekte is aangemeld:
Salbutamolsulfaat
Immuunsisteem Afwykings
Frekwensie onbekend: Hipersensitiwiteitsreaksies, insluitende paradoksale brongospasma, angioedeem, urtikaria, hipotensie en ineenstorting.
Metabolisme en voedingsafwykings
Frekwensie onbekend: Hiperglisemie. Melksuurasidose. Hipokalemie wat vererger kan word deur gepaardgaande behandeling met kortikosteroïede, diuretika, of xantines en deur hipoksie en asidose (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).
Senuweestelsel afwykings
Frekwensie onbekend: Hallusinasie by kinders, hiperaktiwiteit en rusteloosheid.
Kardiale afwykings
Frekwensie onbekend: Tagikardie as gevolg van verhoogde simpatiese uitwerking op die kardiovaskulêre stelsel, hartkloppings. Miokardiale iskemie.
Vaskulêre afwykings
Frekwensie onbekend: Perifere vasodilasie met blosing, hipotensie.
Muskuloskeletale, bindweefsel en been afwykings
Frekwensie onbekend: Fyn tremor van skeletspiere, veral in die hande.
Minder algemeen: Krampe.
Algemene afwykings en toestande by die plek van toediening
Frekwensie onbekend: Hoofpyn en senuspanning.
Bromheksien Hidrochloried
Gastro-intestinale afwykings
Minder algemeen: Gastro-intestinale newe-effekte.
Hepato-bilière afwykings
Frekwensie onbekend: Verbygaande styging in serum aminotransferase waardes.
Vel en subkutaneuse weefsel afwykings
Frekwensie onbekend: Veluitslag.
Algemene afwykings en toestande by die plek van toediening
Frekwensie onbekend: Hoofpyn, duiseligheid, sweet.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Sien **NEWE-EFFEKTE**. 'n Oordosis salbutamol kan tagikardie, stimulasie van die sentrale senustelsel, tremor, hipokalemie, hiperglisemie en melksuurasidose in die liggaam veroorsaak. Behandeling is simptomaties en ondersteunend.
Behandeling met geaktiveerde houtskool kan oorweeg word by pasiënte by wie simptome binne 1 uur van oordosering teenwoordig is.
IDENTIFIKASIE
'n Helder kleurlose, effens viskose vloeistof met 'n lemoengeur.
AANBIEDING
Bruin plastiekbottels (PET) wat 100 mℓ of 200 mℓ bevat. Die bottels is verpak in 'n gedrukte kartonhouer.
BERGINGSAANWYSINGS
Bewaar teen of benede 30 ºC. Beskerm teen lig. Skud bottel voor gebruik.
HOU BUITE BEREIK VAN KINDERS.
REGISTRASIENOMMER
A39/10.1/0390
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
iNova Pharmaceuticals (Pty) Ltd.
Rileyweg 15E, Bedfordview, 2007
DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
Datum van registrasie: 10 Augustus 2007
Datum van laaste hersiening: 23 November 2017

Duro-Tuss® Linctus

Pasiëntinligtingsblad

SKEDULERINGSTATUS
S2
EIENDOMSNAAM, STERKTE EN FARMASEUTIESE FORM
DURO-TUSS LINCTUS - Salbutamolsulfaat 2,41 mg en Bromheksien Hidrochloried 4 mg per 5 mℓ vloeistof
Lees hierdie pamflet sorgvuldig deur omdat dit belangrike inligting vir jou bevat
DURO-TUSS LINCTUS is beskikbaar vir jou gebruik sonder 'n dokter se voorskrif om 'n gematigde kondisie te behandel. Jy moet nogtans **DURO-TUSS LINCTUS** noukeurig gebruik om die beste resultate daaruit te kry.
- Bewaar hierdie pamflet. Jy mag dit dalk weer moet lees.
- Moenie **DURO-TUSS LINCTUS** met enige ander persoon deel nie.
- Vra jou apteker indien jy meer inligting of advies benodig.
- Raadpleeg 'n dokter indien jou simptome vererger of nie beter word na 10 dae van gebruik nie.

WAT DURO-TUSS LINCTUS BEVAT
- Die aktiewe bestanddele is salbutamolsulfaat 2,41 mg en bromheksien hidrochloried 4 mg per 5 mℓ.
  DURO-TUSS LINCTUS bevat versoeter (sukralose 2,5 mg/5 mℓ).
- Die ander bestanddele is sitroensuur, hidroksie-etielsellulose, menthol, lemoengeur, natriumbensoaat, sukralose, propileenglikol en gesuiwerde water.

DURO-TUSS LINCTUS bevat geen suiker of alkohol nie.
WAARVOOR DURO-TUSS LINCTUS GEBRUIK WORD
DURO-TUSS LINCTUS is aangedui vir die verligting van hoes wat gepaard gaan met brongospasma (aamborstigheid).
VOORDAT JY DURO-TUSS LINCTUS GEBRUIK
Moenie DURO-TUSS LINCTUS gebruik:
- as jy hipersensitief (allergies) is vir salbutamol, bromheksien of enige van die ander bestanddele van **DURO-TUSS LINCTUS** nie
- as jou hart onreëlmatig klop (hartdisritmie) of te vinnig klop (tagikardie)
- indien jy monoamienoksidaseremmers (MAOR's) ontvang, of binne 14 dae na die behandeling met MAOR's gestaak is (medisyne vir die behandeling van depressie).

Wees veral versigtig met DURO-TUSS LINCTUS:
Vertel jou dokter as jy ly aan die volgende:
- hipertiroïedisme ('n ooraktiewe skildklier)
- miokardiale ontoereikendheid (wanfunksionering van die hartspier)
- disritmieë (onreëlmatige hartklop)
- vatbaarheid vir verlenging van die QT-interval (die tyd tussen die begin van die Q-golf en die einde van die T-golf in die hart se elektriese siklus)
- hipertensie (hoë bloeddruk)
- geskiedenis van 'n maagseer
- diabetes mellitus
- asma (dit mag nodig wees dat die dokter die kaliumvlakke in jou bloed monitor)
- as jy 'n geskiedenis het van 'n maagseer
- erge lewer- of nierversaking

Hoë dosisse kan die risiko van ernstige newe-effekte verhoog, insluitend onreëlmatige hartklop (kardiale disritmie). Moenie meer as die aanbevole dosis inneem nie. (sien **HOE OM DURO-TUSS LINCTUS TE NEEM**).
Swangerskap en Borsvoeding:
Jy moenie **DURO-TUSS LINCTUS** neem as jy swanger is of borsvoed nie.
Die veiligheid van gebruik van **DURO-TUSS LINCTUS** gedurende swangerskap en borsvoeding is nog nie vasgestel nie.
DURO-TUSS LINCTUS kan die aanvang van kraam vertraag.
As jy swanger is of jou baba borsvoed, raadpleeg jou dokter, apteker of ander gesondheidsdeskundige voordat u hierdie medisyne gebruik.
Die neem van ander medisyne met DURO-TUSS LINCTUS:
Vertel altyd jou gesondheidsorgdeskundige indien jy enige ander medisyne gebruik (Dit sluit die gebruik van komplimentêre of tradisionele medisyne in):
Indien jy ander medikasie op 'n gereelde basis neem, insluitende komplimentêre of tradisionele medisyne, kan die gebruik van **DURO-TUSS LINCTUS** met hierdie medisyne ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of enige ander gesondheidsorgdeskundige vir advies.
Moenie **DURO-TUSS LINCTUS** neem as jy diuretika (watertablette), kortikosteroïede of xantiene gebruik nie.
HOE OM DURO-TUSS LINCTUS TE GEBRUIK
Moenie medisyne wat aan jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **DURO-TUSS LINCTUS** presies soos die dokter aan jou voorgeskryf het. Maak seker by jou dokter of apteker indien jy onseker is.
Die gewone dosis is:
Volwassenes: 10 mℓ (twee medisynemates) drie tot vier maal per dag
Kinders 6 – 12 jaar: 5 mℓ (een medisynemaat) drie tot vier maal per dag
Kinders 2 – 6 jaar: 2,5 mℓ – 5 mℓ (half tot een medisynemaat) drie tot vier maal per dag.
Moenie die aanbevole dosis oorskry nie.

DURO-TUSS LINCTUS is geskik vir kinders, bejaarde en diabetiese pasiënte.
Indien jy onder die indruk is dat die effek van **DURO-TUSS LINCTUS** te sterk of te swak is vir jou, moet jy jou dokter of apteker raadpleeg.
As jy meer DURO-TUSS LINCTUS neem as wat jy moet:
Sommige van die volgende kan ondervind word in die geval van oordosering:
- Tagikardie (vinnige hartklop)
- Tremor
- Bewerigheid Hiperglisemie (hoë bloedsuiker)
- Verhoogde melksuur konsentrasies (melksuurasidose)

Kontak jou dokter of apteker in geval van oordosering. Soek hulp by die naaste hospital of gifbeheersentrum indien nie een van hulle beskikbaar is nie.
As jy vergeet om DURO-TUSS LINCTUS te neem:
Moenie 'n dubbele dosis neem om op te maak vir 'n vergete individuele dosis.nie.
MOONTLIKE NEWE-EFFEKTE
DURO-TUSS LINCTUS kan newe-effekte hê:
Nie alle newe-effekte wat aangemeld is vir **DURO-TUSS LINCTUS**, word in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg wanneer jy hierdie medisyne gebruik, raadpleeg jou dokter, apteker of ander gesondheidsorgdeskundige vir raad.
Indien enige van die volgende gebeur, staak die gebruik van **DURO-TUSS LINCTUS** en vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- hipersensitiwiteitsreaksies (allergiese reaksies)
- asemhalingsprobleme wat volg na die gebruik van 'n inhalasiemiddel (paradoksikale brongospasma)
- swelling (angioedeem)
- veluitslag (urtikarie)
- lae bloeddruk (hipotensie)
- floutes (ineenstorting)
- verhoogde melksuur konsentrasies (melksuurasidose).

Bogenoemde is almal baie ernstige newe-effekte. Indien jy almal ervaar, het jy moontlik 'n erge allergiese reaksie teenoor **DURO-TUSS LINCTUS**. Jy mag dringende mediese aandag of hospitalisasie benodig.
Vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- hoë bloedsuiker
- lae kaliumvlakke in die bloed
- as jou hart te vinnig klop
- sterk, ongereelde hartklop
- verminderde bloedvloei na jou hart
- blosing
- 'n verhoging in sekere lewerensieme.

Bogenoemde is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.
Die volgende newe-effekte is aangemeld (frekwensie onbekend), vertel jou dokter as jy enige van die volgende opmerk:
- hallusinasies by kinders
- hiperaktiwiteit en rusteloosheid
- fyn bewing van die spiere, veral die hande
- krampe
- hoofpyn
- senuweespanning
- gastro-intestinale newe-effekte
- veluitslag
- duiseligheid
- sweet.

Indien jy enige van die newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet jy asseblief jou dokter of apteker in kennis stel.
BERGING EN WEGDOENING VAN DURO-TUSS LINCTUS
Bewaar teen of benede 30 °C.
Beskerm teen lig. Skud bottel voor gebruik.
Hou alle medisyne buite die bereik en sig van kinders.
Moenie na die vervaldatum wat op die etiket en karton aangedui word gebruik nie.
Alle ongebruikte medisyne moet terugbesorg word aan jou apteker.
Moenie enige ongebruikte medisyne in dreine of rioolstelsels weggooi nie.
AANBIEDING VAN DURO-TUSS LINCTUS
Bruin plastiekbottels (PET) wat 100 mℓ of 200 mℓ bevat. Die bottels is verpak in 'n gedrukte kartonhouer.
IDENTIFIKASIE VAN DURO-TUSS LINCTUS
'n Helder kleurlose, effens viskose vloeistof met 'n lemoengeur.
REGISTRASIENOMMER
A39/10.1/0390
NAAM EN ADRES VAN DIE REGISTRASIEHOUER
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