PATIENT INFORMATION LEAFLET

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

This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use BISOLVON LINCTUS DA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days. If you have difficulty breathing or become breathless, you must consult a doctor immediately.

SCHEDULING STATUS **S2**

Bisolvon® Linctus DA

Bromhexine hydrochloride
Orciprenaline sulphate

1. WHAT BISOLVON LINCTUS DA CONTAINS

- The active substances per 5 ml are 4 mg bromhexine (brom-hex-een) hydrochloride and 5 mg orciprenaline (or-ci-pren-a-leen) sulphate.

- The other ingredients are cocoa flavouring agent, disodium edetate dihydrate, hydroxyethylcellulose, methylparaben 0,05 % *m/v* (preservative), propylparaben 0,01 % *m/v* (preservative), purified water, sorbitol and a small quantity of hydrochloric acid as a pH adjuster.
  This medicine is sugar free.

2. WHAT BISOLVON LINCTUS DA IS USED FOR

Bromhexine belongs to a group of medicines called mucolytics (medicines that help dissolve mucus or phlegm). Orciprenaline belongs to a group of medicines called bronchodilators (medicines that open the air passages of the lungs).

BISOLVON LINCTUS DA is used to relieve a wet (phlegmy) cough that is associated with wheezing or a tight chest.

3. BEFORE YOU TAKE BISOLVON LINCTUS DA

Do not take BISOLVON LINCTUS DA:

- If you are hypersensitive (allergic) to bromhexine hydrochloride, orciprenaline sulphate or any of the other ingredients of BISOLVON LINCTUS DA.
- If you are hypersensitive (allergic) to any asthma medicines please check with your doctor or pharmacist before taking BISOLVON LINCTUS DA.
- If you have an overactive thyroid gland.
- If you have any problems with your heart including an enlarged heart muscle and palpitations or rapid heartbeat.

Take special care with BISOLVON LINCTUS DA:

- If you are using any other medicines, please check with your doctor or pharmacist before taking BISOLVON LINCTUS DA.
- If you have epilepsy or seizure disorders.
- If you have a stomach ulcer or have had stomach ulcers in the past.
- If you have asthma.
- If you have poorly controlled sugar diabetes (diabetes mellitus) or high blood pressure.
- If you have problems with your kidneys, liver, heart (including abnormal heart beat), blood circulation, adrenal glands, thyroid gland or prostate.
- If you have glaucoma (high pressure in the eyes) or angina (chest pain).

If you are battling to breathe or are breathless, you should consult a doctor immediately.

If you are coughing up phlegm that is green or brown; or pink and foamy or contains blood you should consult a doctor immediately.

If your condition worsens it could be dangerous to increase the dose of BISOLVON LINCTUS DA over a long time. You should consult your doctor so that your therapy can be reviewed. High doses may cause serious side effects including effects on your heart.

Pregnancy and Breastfeeding:
Safety in pregnancy and breastfeeding has not been shown.
If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:
BISOLVON LINCTUS DA may cause dizziness. Make sure you know how you react to this medicine before you drive or operate machines.

Taking other medicines with BISOLVON LINCTUS DA:
If you are taking other medicines on a regular basis, including medicines bought over the counter, complementary or traditional medicines, the use of BISOLVON LINCTUS DA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

BISOLVON LINCTUS DA can interfere with:

- Certain medicines used to treat heart disease (cardiac glycosides and quinidine) and high blood pressure (diuretics and beta-blockers).
- Inhaled anaesthetics. Before you have any surgery, tell the doctor that you are taking BISOLVON LINCTUS DA.
- Certain medicines used to treat depression (monoamine oxidase inhibitors and tricyclic antidepressants).

- Some cold and flu products, some medicines used to treat asthma and some medicines used for weight loss may add to the effects of BISOLVON LINCTUS DA.

4. HOW TO TAKE BISOLVON LINCTUS DA

Always take BISOLVON LINCTUS DA exactly as your doctor or pharmacist has instructed you. Do not take more BISOLVON LINCTUS DA than recommended. Do not take BISOLVON LINCTUS DA more often than recommended. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that BISOLVON LINCTUS DA is too strong or too weak, talk to your doctor or pharmacist.

The usual dosage of BISOLVON LINCTUS DA is:

- *Adults and children over 12 years:* 10 to 20 ml (two to four medicine measures) three times a day.
- *Children 3 - 12 years:* 5 to 10 ml (one to two medicine measures) three times a day.
- *Children under 3 years:* 2,5 to 5 ml (one-half to one medicine measure) three times a day.

If you take more BISOLVON LINCTUS DA than you should:

Overdosage may cause symptoms such as heart palpitations or a rapid heartbeat, irregular heartbeat, shaking, high or low blood pressure, chest pain or flushing.

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 BISOLVON LINCTUS DA:

Take it as soon as you remember. However, if it is nearly time to take your next dose, skip the missed dose and go back to your normal dosing schedule.
Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

BISOLVON LINCTUS DA can have side effects.

BISOLVON LINCTUS DA may cause:

- Nausea and vomiting
- Headache, dizziness and sweating
- Skin reactions, allergic reactions
- Tremor (shaking), nervousness or muscle cramps
- Palpitations, rapid or irregular heartbeat
- Difficulty in passing urine

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

- Chest pain (angina), tightness of the chest

- Difficulty breathing or worsening asthma
- Allergic reactions such as itchy skin rash (hives), swelling of the face, lips, mouth, tongue, throat, or difficulty in breathing.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.

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

6. STORING AND DISPOSING OF BISOLVON LINCTUS DA

Keep all medicines out of reach and sight of children.
Store BISOLVON LINCTUS DA in a cool place (at or below 25 °C).
Keep BISOLVON LINCTUS DA in its original bottle until needed. Keep the container tightly closed.

Do not take this medicine after the expiry date stated on the bottle. Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF BISOLVON LINCTUS DA

Bottles of 100 ml and 200 ml.

8. IDENTIFICATION OF BISOLVON LINCTUS DA

BISOLVON LINCTUS DA is a clear, colourless liquid with a cocoa odour.

9. REGISTRATION NUMBER

B/10.1/18

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

sanofi-aventis south africa (pty) ltd
2 Bond Street, 1685, Midrand, South Africa
Tel. No.: +27-11-256 3700

Manufacturer:
Zentiva South Africa (Pty) Ltd
315 Waltloo Rd, Waltloo, Pretoria
South Africa

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

7 July 2006.

INLIGTINGSBLAD VIR PASIËNTE_____

Lees die hele pamflet noukeurig deur, want dit bevat inligting wat belangrik is vir jou
Hierdie medisyne word sonder ’n doktersvoorskrif aan jou beskikbaar gestel om self jou ligte aandoenings te behandel. Jy moet nogtans BISOLVON LINCTUS DA versigtig gebruik om die beste resultate daarmee te kan behaal.

- Hou hierdie pamflet. Jy sal dit dalk benodig om dit te weer te lees.
- Raadpleeg jou dokter of apteker indien jy nog inligting of raad benodig.
- Jy moet ’n dokter spreek as jou simptome versleg of nie na 7 dae verbeter nie. Indien jy moeilik asemhaal, of kortasem raak, moet jy dadelik ’n dokter spreek.

SKEDULERINGSTATUS **S2**

Bisolvon® Linctus DA

(Sanofi logo)

Broomheksienhidrochloried
Orsiprenaliensulfaat

1. WAT BISOLVON LINCTUS DA BEVAT

- Die aktiewe bestanddele per 5 ml is 4 mg broomheksien (broom-hek-sien) - hidrochloried en 5 mg orsiprenalien (or-si-pre-na-lien) -sulfaat.

- Die ander bestanddele is kakao-geurmiddel, dinatriumedetaatdihidraat, hidroksi-etielsellulose, metielparabeen 0,05 % *m/v* (preserveermiddel), propielparabeen 0,01 % *m/v* (preserveermiddel), gesuiwerde water, sorbitol en ‘n klein hoeveelheid soutsuur vir pH - instelling.
  Hierdie medisyne is suikervry.

2. WAARVOOR BISOLVON LINCTUS DA GEBRUIK WORD

Broomheksien behoort tot ’n groep medisyne wat bekend staan as mukolitika (medisyne wat help om mukus of slym op te los). Orsiprenalien behoort tot ’n groep medisyne, bekend as brongodilators (medisyne wat die lugpype in die longe oopmaak).

BISOLVON LINCTUS DA word gebruik om ’n nat (slym-belaaide) hoes, wat geassosieer word met ‘n fluitende of benoude bors, te verlig.

3. VOORDAT JY BISOLVON LINCTUS DA GEBRUIK

Moenie BISOLVON LINCTUS DA neem nie:

- Indien jy hipersensitief (allergies) is vir broomheksienhidrochloried, orsiprenaliensulfaat of enige ander bestanddeel van BISOLVON LINCTUS DA nie.
- Indien jy hipersensitief (allergies) is vir enige asmamedisyne, klaar asseblief eers onsekerhede op met jou dokter of apteker voordat jy BISOLVON LINCTUS DA neem.

- Indien jy ’n ooraktiewe skildklier het.
- Indien jy enige hartprobleme het, insluitende vergrote hartspier en hartkloppings of vinnige hartslag.

Neem sorg met die gebruik van BISOLVON LINCTUS DA:
- Indien jy enige ander medisyne gebruik, gaan dit eers na met jou dokter of apteker voordat jy BISOLVON LINCTUS DA neem.
- Indien jy epilepsie of stuipe kwale het.
- Indien jy tans ’n maagsweer het, of voorheen maagswere gehad het.
- Indien jy aan asma ly.
- Indien jy swak beheerde suiker diabetes (diabetes mellitus) of hoë bloeddruk het.
- Indien jy probleme met jou niere, lewer, hart (insluitende abnormale hartklop), bloedsirkulasie, byniere, skildklier of prostaat ondervind.
- Indien jy gloukoom (hoë druk in die oë) of angina (borspyn) het.

Indien jy sukkel om asem te haal of kortasem is, moet jy dadelik ’n dokter raadpleeg.

Indien jy groen of bruin, of pienk en skuimerige of bloederige slym uithoes, moet jy dadelik ’n dokter raadpleeg.

Indien jou toestand agteruit gaan kan dit gevaarlik wees om die BISOLVON LINCTUS DA dosis oor ’n lang tydperk te verhoog. Jy moet jou dokter spreek sodat jou terapie hersien kan word. Hoë dosisse kan ernstige newe-effekte, insluitende effekte op jou hart, veroorsaak.

Swangerskap en borsvoeding:
Veiligheid met swangerskap en borsvoeding is nie aangetoon nie.
Indien jy swanger is of jou baba borsvoed terwyl jy hierdie medisyne neem, nader asseblief jou dokter, apteker of ander gesondheidsorgkundige om advies.

Bestuur en gebruik van masjinerie:
BISOLVON LINCTUS DA kan duiseligheid veroorsaak. Maak seker dat jy weet hoe jy op hierdie medisyne reageer voordat jy bestuur of masjinerie hanteer.

Gebruik van ander medisyne met BISOLVON LINCTUS DA:
Indien jy ander medisyne op ’n gereelde grondslag neem, insluitende medisyne wat jy oor die toonbank gekoop het, komplimentêre of tradisionele medisyne, kan die gebruik van BISOLVON LINCTUS DA saam met hierdie medisyne ongewenste interaksies veroorsaak. Nader asseblief jou dokter, apteker of ander gesondheidsorgkundige om advies.

BISOLVON LINCTUS DA kan met die volgende inmeng:
- Sekere medisyne wat gebruik word om hartsiekte te behandel (hartglikosiede en kinidien) en hoë bloeddruk (diuretika en beta-blokkeerders).
- Ingeasemde narkosemiddels. Voordat jy enige chirurgie ondergaan moet jy jou dokter inlig dat jy BISOLVON LINCTUS DA gebruik.

- Sekere medisyne wat gebruik word om depressie te behandel (mono-amienoksidase remmers en trisikliese antidepressante).
- Sommige verkoue- en griepprodukte, sommige medisyne wat gebruik word om asma mee te behandel en sommige medisyne wat gebruik word vir gewigsverlies kan tot die effekte van BISOLVON LINCTUS DA bydra.

4. HOE OM BISOLVON LINCTUS DA TE NEEM

Neem altyd BISOLVON LINCTUS DA presies soos wat jou dokter of apteker aan jou voorgeskryf het. Moenie meer BISOLVON LINCTUS DA neem as wat aanbeveel word nie. Moenie BISOLVON LINCTUS DA meer dikwels neem as wat aanbeveel word nie. Jy moet enige onsekerhede met jou dokter of apteker opklaar.

Indien jy die indruk kry dat BISOLVON LINCTUS DA te sterk of te swak is, praat daaroor met jou dokter of apteker.

Die gewone dosis van BISOLVON LINCTUS DA is:

- *Volwassenes en kinders ouer as 12 jaar:* 10 tot 20 ml (twee- tot vier medisynemates) drie keer per dag.
- *Kinders 3 - 12 jaar:* 5 tot 10 ml (een tot twee medisynemates) drie keer per dag.
- *Kinders onder 3 jaar:* 2,5 tot 5 ml (’n half - tot een medisynemate) drie keer per dag.

Indien jy meer BISOLVON LINCTUS DA geneem het as wat jy moes:
Oordosering kan simptome soos hartkloppings of ’n vinnige hartslag, onreëlmatige hartklop, bewerasie, hoë of lae bloeddruk, borspyn of gloede veroorsaak.

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kry hulp by die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet het om BISOLVON LINCTUS DA te neem:
Neem dit sodra jy onthou. As dit egter amper tyd is om jou volgende dosis te neem, los die oorgeslaande dosis uit en hervat weer jou normale dosisplan.
Moenie ’n dubbeldosis neem om op te maak vir individuele dosisse wat vergeet is nie.

5. MOONTLIKE NEWE-EFFEKTE

BISOLVON LINCTUS DA kan newe-effekte hê.

BISOLVON LINCTUS DA kan die volgende veroorsaak:

- Naarheid en braking
- Hoofpyn, duiseligheid en sweet
- Velreaksies, allergiese reaksies
- Tremor (bewerasie), senuweeagtigheid of spierkrampe
- Hartkloppings, vinnige of onreëlmatige hartklop
- Probleme om urine te passeer

Sê dadelik vir jou dokter, of gaan na die ongevalle afdeling van jou naaste hospitaal as jy enige van die volgende ervaar:

- Borspyn (angina), benoude bors
- Moeilike asemhaling of verslegting van asma
- Allergiese reaksies soos jeukerige vel (galbulte), geswelde gesig, lippe, mond, tong, keel, of probleme met asemhaling.

Nie alle newe-effekte wat vir hierdie medisyne aangemeld is, is by hierdie voubiljet ingesluit nie. Indien jou algemene gesondheid agteruitgaan terwyl jy hierdie medisyne neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige.

Indien jy enige newe-effekte waarneem wat nie in hierdie voubiljet vermeld word nie, lig asseblief jou dokter of apteker in.

6. BERGING EN WEGDOENING VAN BISOLVON LINCTUS DA

Hou alle medisyne buite bereik en sig van kinders.
Bewaar BISOLVON LINCTUS DA op ’n koel plek (teen of benede 25 °C).
Bewaar BISOLVON LINCTUS DA in die oorspronklike bottel totdat dit benodig word.
Hou die bottel altyd dig toe.

Moenie hierdie medisyne ná die vervaldatum wat op die bottel aangedui word, gebruik nie. Besorg alle ongebruikte medisyne of medisyne wat verval het terug aan jou apteker vir veilige wegdoening. Moenie ongebruikte medisyne in afvoer- of rioolstelsels (bv. toilette) gooi nie.

7. AANBIEDING VAN BISOLVON LINCTUS DA

Bottels met 100 ml en 200 ml.

8. IDENTIFIKASIE VAN BISOLVON LINCTUS DA

BISOLVON LINCTUS DA is ’n helder, kleurlose vloeistof met ’n kakaogeur.

9. REGISTRASIENOMMER

B/10.1/18

10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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11. DATUM VAN PUBLIKASIE VAN DIE INLIGTINGSBLAD VIR PASIËNTE

07 Julie 2006.