MAVILEX TABLET

Clenbuterol hydrochloride 0.02mg

What is in the leaflet?

- 1. What MAVILEX is used for
- 2. How MAVILEX works
- 3. Before you use MAVILEX
- 4. How to use MAVILEX
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of MAVILEX
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of Revision

What MAVILEX is used for

MAVILEX is used in people with asthma, bronchitis (inflammation or swelling of bronchial tubes) and other breathing problem.

Ask your doctor if you have any questions about why MAVILEX has been prescribed for you.

Your doctor may prescribe it for another reason.

How MAVILEX works

MAVILEX contains clenbuterol hydrochloride. Clenbuterol is a bronchodilator and belongs to a group of medicines called beta-2-agonists.

MAVILEX is used to open up the airways so that you can breathe more easily.

Before you use MAVILEX

When you must not use it

Do not take MAVILEX if you

have ever had an allergic reaction to:

 any medicine containing clenbuterol or any other medicines used to treat breathing problems. • any of the ingredients listed at the end of this leaflet.

Do not take MAVILEX after the expiry date (EXP) printed on the pack.

Do not take it if the bottle shows signs of having been tampered with.

If you are not sure whether you should start using this medicine, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have any of the following medical conditions:

- heart problems
- hypertension (high blood pressure)
- diabetes
- thyroid problems

It may not be safe for you to take MAVILEX if you have any of these conditions.

Tell your doctor if you are pregnant or plan to become pregnant, or breastfeeding.

Your doctor will advise you of the risks and benefits of using MAVILEX during pregnancy and while breastfeeding.

If you have not told your doctor about any of these things, tell them before you take MAVILEX.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and MAVILEX may interfere with each other. These include:

 medicines used to treat heart problems or high blood pressure

Your doctor or pharmacist has a more complete list of medicines to be careful with or avoid while taking MAVILEX.

How to use MAVILEX

How much to use

The recommended total daily dose for adults and children over 12 years is 0.04 mg / day. In severe bronchial spasm (bronchial spasm is a sudden constriction of the muscles in the walls ofbronchioles) the dose may be increased to 0.08 mg / day daily; as therapy continues, the dose may often be reduced to 0.02 mg / day.

Adults and children over 12 years: Take one tablet (0.02 mg) twice daily.

When to use it

Twice daily doses to be taken in the morning and evening.

How long to use it

The duration of treatment depends upon the symptoms and there is no objection to long-term treatment.

Continue using MAVILEX for as long as your doctor tells you.

Do not miss any doses and do not stop taking the medicine even if you feel better. Missing doses may make your symptoms worse.

Individuals will vary greatly in their response to MAVILEX. Your doctor will check your progress at regular intervals.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose) Immediately telephone your doctor or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much MAVILEX. Do this even if there are no signs of

You may need urgent medical attention.

While you are using it

discomfort or poisoning.

<u>Things you must do</u>
Take MAVILEX exactly as your doctor has prescribed.

They may differ from the information contained in this

leaflet.

If you find that the usual dose

of MAVILEX is not giving

you as much relief as before, or you need to use it more often, please contact your doctor so that your condition can be checked.

This is important to ensure your breathing problem is controlled properly.

See your doctor regularly to ensure that your asthma is not getting worse.

Tell any other doctors, dentists and pharmacists who are treating you that you are using MAVILEX.

If you are about to be started on a new medicine, tell your doctor or pharmacist that you are using MAVILEX.

If you become pregnant while using MAVILEX, tell your doctor or pharmacist.

Things you must not do

Do not take any other medicines for your breathing problems without checking with your doctor

Do not give MAVILEX to anyone else, even if they have the same or a similar condition to you.

Do not use MAVILEX to treat any other complaints unless your doctor tells you to.

Things to be careful of

Visit your doctor or health care professional for regular checkups. Tell your doctor if your symptoms do not improve.

Do not take extra doses. If your asthma or bronchitis gets worse while you are using this medicine, call your doctor right away.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MAVILEX.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- tremor (shaky hands)
- nervousness
- increased heart rate or palpitations
- nausea (feeling sick), vomiting or diarrhoea
- drowsiness or dizziness
- agitation

These side effects are usually mild.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of MAVILEX

Storage

Keep MAVILEX in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and a-half metres above the ground is a good place to store medicines.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

An oval, scored tablet, white in colour with markings 'DUO' and '861'.

Ingredients

Active ingredient:

• Clenbuterol Hydrochloride

Inactive ingredients:

- Aerosil
- Promigel
- Corn starch
- Polyvinyl pyrollidone
- Lactose
- Magnesium stearate

MAL number MAL19971843A

Manufacturer

DUOPHARMA (M) SDN. BHD. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

DUOPHARMA (M) SDN. BHD. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Date of Revision 08/04/2014