

# DUOLIN METERED DOSE INHALER

Salbutamol sulphate/Ipratropium bromide (100mcg/20mcg per actuation)

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## What DUOLIN INHALER is used for

The name of your medicine is DUOLIN INHALER. It is used for the management of reversible bronchospasm (narrowing of the airways going into the lungs) associated with obstructive airway disease in people who requires more than a single bronchodilator (widening of the airways).

## How DUOLIN INHALER works

DUOLIN INHALER contains two different medicines called:

- Ipratropium bromide and
- Salbutamol sulphate

Both belong to a group of medicines called bronchodilators. They work by relaxing the muscles around the airways so that they open and you can breathe more easily

## Before you use DUOLIN INHALER

### -When you must not use it

Do not use DUOLIN INHALER if:

- You are allergic (hypersensitive) to ipratropium or salbutamol or any of the other ingredients in DUOLIN INHALER.
- You have a heart problem called 'hypertrophic obstructive cardiomyopathy'. This is where the wall between the two sides of the heart gets bigger and blocks the blood flow.
- You have a very fast heart beat (called 'tachyarrhythmia')
- You are allergic to soya lecithin or related food products like soyabean and peanuts.

### -Before you start to use it

Check with your doctor or pharmacist before using this medicine if:

- You have glaucoma (increased pressure inside the eye), or have been told that you may develop it
- You have heart or circulation problems, or have had a recent heart attack
- You have diabetes
- You have an over-active thyroid gland
- You have ever had something called 'pheochromocytoma'. (rare tumor of the adrenal glands)
- You are a man who has enlarged prostate problems
- You have cystic fibrosis (progressive, genetic disease that causes persistent lung infections and limits the ability to breathe over time)

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before using DUOLIN INHALER.

### Pregnancy and breastfeeding

Duolin should not be used in pregnancy, especially the first trimester or if you are breastfeeding unless the expected benefits outweigh any possible risk to the newborn. Ask your doctor for advice before taking any medicine

### -Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because DUOLIN INHALER can affect the way some other medicines work. Also, some other medicines can affect the way DUOLIN INHALER works. Tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroid medicines
- Water tablets (also called 'diuretics')
- Medicines for depression (such as tricyclic antidepressants or monoamine oxidase inhibitors)
- Xanthine derivatives (Medicines to help your breathing)
- Medicines called 'anti- cholinergics'.
- Medicines called 'beta blockers'. These can be used to treat heart

problems, high blood pressure or migraine

- Digoxin - used for a fast heart beat or heart failure

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using DUOLIN INHALER.

### Operations

Some gases used in operations (anaesthetic gases such as halothane, trichloroethylene and enflurane) may affect how your medicine works. If you are about to have surgery, make sure you mention that you are taking DUOLIN INHALER to the doctor, dentist or anaesthetist.

## How to use DUOLIN INHALER

### -How much to use it

Always use DUOLIN INHALER exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Follow these instructions to get the best results. If anything is unclear after reading this leaflet, ask your doctor, pharmacist or nurse

### **Adults (including the elderly) and children over 12 years:**

The recommended dose is 2 inhalations, 4 times a day.

DUOLIN INHALER is not recommended for children under 12 years.

### When to use it

It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

### -How long to use it

Use your inhaler for the duration for which your doctor has prescribed.

### -If you forget to use it

- If you forget a dose, take it as soon as you remember it
  - However, if it is time for the next dose, skip the missed dose
  - Do not take a double dose to make up for a forgotten dose
- If you have any further questions, ask your doctor or pharmacist.

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## -If you use too much (overdose)

Contact your doctor immediately or go to

the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking too much may cause lower potassium levels in your blood, chest pain, high blood pressure and fast heart beat

## **While you are using it**

### -Things you must do

If the recommended dose does not provide the desired effect, consult your doctor. It is dangerous to exceed the recommended dose. Do not use more than your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Duolin Inhaler. Tell your doctor immediately if you become pregnant while taking this medication. Consult a doctor immediately in the event of acute, rapidly worsening breathing difficulty

### -Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor or pharmacist. Do not give Duolin to anyone else, even if they have the same symptoms or condition as you

### -Things to be careful of

See your doctor straight away if you feel that your medicine is not working as well as usual. Your doctor may need to check how well your medicine is working. Care must be taken to prevent Duolin from entering the eye

## **Side effects**

Like all medicines, DUOLIN INHALER can cause side effects, although not everybody gets them.

- If after taking DUOLIN INHALER, you are wheezy or have other difficulties in breathing, do not take any more (unless

you have been told to by your doctor)

- nervousness
- tremor
- tachycardia (abnormally rapid heart rate)
- dizziness
- palpitations (pounding of heartbeat)
- headache
- dryness of mouth, throat irritation, dysphonia (difficulty in speaking)
- paradoxical bronchoconstrictions (rapid onset of unexpected narrowing of the airways occurring shortly after the use of a medicine)
- nausea, vomiting, sweating, weakness, muscle cramps
- high or low blood pressure
- eye complications such as dilation of the pupil, increased pressure inside the eye, eye pain & blurred vision if it enters the eyes
- gastrointestinal disturbance
- urinary retention
- allergic reactions such as skin rash, itching, angioedema (swelling of the deeper layers of the skin) of the tongue, lips, face, hives, laryngospasm (brief spasm of the vocal cords)
- anaphylactic reactions (potentially life-threatening allergic reactions)
- hyperactivity in children

Some of it is just mild side effects, not necessary need to see doctor.

If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public --> Reporting Medicinal Problems / Side Effects / AEFI/Vaccine Safety).

## **Storage and Disposal of DUOLIN INHALER**

### -Storage

Store below 30°C. Protect from frost. Do not use this medicine after the expiry date

which is stated on the carton and the inhaler label. The expiry date refers to the last day of the month. Keep inhaler in the outer carton to protect from light. Keep out of the sight and reach of children.

### -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

Duolin CFC free inhaler is a one piece filled metal container fitted with a valve with plastic stem. On visual examination, there should be no sign of physical damage such as dents, bulged containers bent valve stem and uneven crimping. A white coloured powder is obtained after opening the container.

### -Ingredients

- Active ingredients: Ipratropium bromide and Salbutamol sulphate
- Inactive ingredients: Lactose monohydrate (micronised) and Heptafluoropropane (HFA- propellant 227)

-MAL Number: MAL07082851AZ

## **Manufacturer**

Cipla Ltd.  
Verna Industrial Estate,  
Goa 403722 India

## **Product Registration Holder**

Cipla Malaysia Sdn Bhd  
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