Patient Information Leaflet

Information for the Patient about

DUOLIN HFA (METERED DOSE INHALER)

Read all of this leaflet carefully before you start using DUOLIN HFA.

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **DUOLIN HFA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

SCHEDULING STATUS:

S3

PROPRIETARY NAME (AND DOSAGE FORM):

DUOLIN HFA (Metered dose inhaler)

WHAT DUOLIN HFA CONTAINS:

Each metered dose contains ipratropium bromide monohydrate equivalent to ipratropium 20 mcg and salbutamol sulphate equivalent to salbutamol 100 mcg in each actuation.

Inactive ingredients include HFA-227 propellant gas and lactose monohydrate.

Contains lactose.

WHAT DUOLIN HFA IS USED FOR:

DUOLIN HFA belongs to a class of medicines called bronchodilators, which improve

breathing by opening up airways.

DUOLIN HFA is used to treat constriction of the airways or bronchospasm (tightness of the chest or wheezing).

BEFORE YOU USE DUOLIN HFA:

Do not use DUOLIN HFA if:

- You are hypersensitive (allergic) to ipratropium bromide or salbutamol; or any of the other components of **DUOLIN HFA**.
- You have been diagnosed with an enlarged heart or heart muscle disease or if your heart is beating too fast.
- You are hypersensitive (allergic) to soya lecithin or related food products, such as soybean and peanut.
- You are hypersensitive (allergic) to atropine or its derivatives.
- You are pregnant or breastfeeding your baby (see **"Pregnancy and breastfeeding"**).

Safety in children has not been established.

Take special care with DUOLIN HFA:

Immediate hypersensitivity (allergic) reactions may occur after use of **DUOLIN HFA**. Please report any of the following symptoms to your doctor as a matter of urgency: hives and itching, swelling of the lips, tongue, face or any other body part, skin rash, tightness of the chest with wheezing or swelling of the throat with difficult breathing (see **"POSSIBLE SIDE-EFFECTS"**).

***Eye complications*:**

You may experience eye complications if the aerosol from **DUOLIN HFA** comes into contact with your eyes. It is important that you use **DUOLIN HFA** correctly and that you ask your doctor or pharmacist for assistance if you struggle to master the inhalation technique. Eye complications include dilation of the pupil and raised pressure inside the eye leading to glaucoma (a condition caused by raised pressure inside the eye and presenting with severe eye pain, blurred vision, halos around objects and red eyes) or eye pain (see **"POSSIBLE SIDE-EFFECTS"**). Please report any of these symptoms to your doctor as a matter of urgency. If you have previously been told that you are at risk of developing glaucoma, you should take particular care to protect your eyes from coming into contact with the aerosol.

The presence of certain medical conditions requires that you be especially careful when you use **DUOLIN HFA**. Please discuss the use of **DUOLIN HFA** with your doctor if:

- You have diabetes mellitus (high blood sugar) which is not properly controlled.
- You recently had a heart attack.
- You have a serious heart disorder or disorder of your blood vessels.
- You have an overactive thyroid gland.
- You have been diagnosed with a tumour of your adrenal gland.
- You are predisposed to narrow-angle glaucoma (see above).
- Your prostate is enlarged or you have bladder-neck obstruction (struggle to pass urine).

Please inform your doctor immediately if you suddenly find it increasingly difficult to breathe or if you suddenly develop severe wheezing.

If your airways become increasingly constricted and you find it increasingly difficult to breathe, you should not simply increase the use of **DUOLIN HFA** beyond the dose recommended by your doctor. This may be dangerous to your health. Please consult your doctor if you have to use higher than recommended doses to control your symptoms.

The salbutamol in **DUOLIN HFA** may cause potentially serious lowering of your blood potassium levels, which may result in abnormal heart rhythms. You are at higher risk of developing low blood potassium levels if you are also receiving treatment with xanthine derivates, such as theophylline, corticosteroids (e.g. cortisone) and diuretics (water pills) (see **"Taking other medicines with DUOLIN HFA"**). In addition, if your chest is very tight, low oxygen levels may worsen the influence of low blood potassium levels on your heart rhythm.

If you have cystic fibrosis, you are more likely to experience constipation or other gut disturbances with the use of **DUOLIN HFA**.

Pregnancy and breastfeeding:

Do not use **DUOLIN HFA** if you are pregnant and breastfeeding your baby, as safety has not been established (see **"Do not use DUOLIN HFA if"**).

If you are pregnant or breastfeeding your baby while using DUOLIN HFA, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

DUOLIN HFA is unlikely to affect your ability to drive or operate machinery.

Important information about some of the ingredients in DUOLIN HFA:

DUOLIN HFA contains lactose. If you are lactose intolerant, please speak to your doctor or pharmacist before using **DUOLIN HFA**. If you suffer from a condition known as hereditary galactose intolerance, or if you have a history of galactose intolerance, you should not use **DUOLIN HFA**. You should also not use **DUOLIN HFA** if you suffer from the rare Lapp lactase deficiency or from glucose-galactose malabsorption.

Taking other medicines with DUOLIN HFA:

See **"BEFORE YOU USE DUOLIN HFA"**.

If you are currently taking any of the following medicines, please discuss their use with your doctor or pharmacist:

- Xanthine derivatives, such as theophylline, to open up the airways (see **"Take special care with DUOLIN HFA"**).
- Medicines known as beta-agonists, such as salbutamol, salmeterol or formoterol, to open up the airways.
- Corticosteroids, such as cortisone (see **"Take special care with DUOLIN HFA"**).

- Diuretics, or water pills (see **"Take special care with DUOLIN HFA"**).
- Monoamine oxidase inhibitors or tricyclic antidepressants for the treatment of depression or mood disorders.

If you are taking digoxin, you may experience an increased risk of developing abnormal heart rhythms in the presence of low blood potassium levels. You will be required to go for blood tests to evaluate your blood potassium levels in such instances.

If you take beta-blockers, **DUOLIN HFA** may become less effective (see **"Taking other medicines with DUOLIN HFA"**).

If you are scheduled for surgery with general anaesthesia, please inform the anaesthetist that you are using **DUOLIN HFA**.

If you are taking other medicines that cause dry mouth, constipation, double vision, dry skin or flushing, rapid heart rate and difficulty to pass urine, use of **DUOLIN HFA** may make it worse.

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

HOW TO USE DUOLIN HFA:

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

Always use DUOLIN HFA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults (including elderly patients):	Two inhalations four times a day. The dose may be increased as required up to a limit of 12 inhalations in 24 hours.
Children:	There is no experience of the use of **DUOLIN HFA** in children below the age of 12 years.

Do not exceed the recommended dose.

You should consult a doctor or the nearest hospital immediately if suddenly your airways become increasingly constricted and you find it increasingly difficult to breathe or if additional inhalations do not produce an adequate improvement (see **"Take special care with DUOLIN HFA"**).

The correct operation of the metered dose inhaler is essential for successful therapy. Please speak to your doctor or pharmacist if you are unsure.

Shake the aerosol canister and depress the valve two times before the apparatus is initially used.

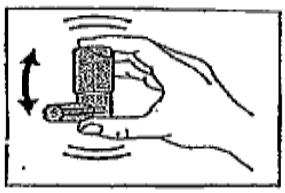


Fig 1

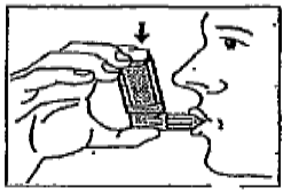


Fig 2

Instructions for use:

1. Remove the protective cap.
2. Shake the metered dose inhaler well before each use (see Fig 1).
3. Breathe out deeply.
4. Hold the metered dose inhaler as shown in Fig 2, and close lips over the mouthpiece. The arrow and the base of the container should be pointing upwards.
5. Breathe in as deeply as possible, pressing the base of the container firmly at the same time, this releases one metered dose. Hold the breath for a few seconds, then remove the mouthpiece from the mouth and breathe out. The same action should be repeated for a second inhalation.
6. Replace the protective cap after use.

The container is under pressure and should on no account be opened by force or exposed to temperatures exceeding 50 ℃. As the container is not transparent it is not possible to see when the contents are used up, but shaking the container will show if there is any remaining fluid. The mouthpiece should always be kept clean and can be washed with warm water. If soap or detergent is used, the mouthpiece should be thoroughly rinsed in clear water.

If you use more DUOLIN HFA than you should:

If you use more **DUOLIN HFA** than you should, you may develop rapid heart rate, palpitations, tremor, high blood pressure or low blood pressure, chest pain on exertion, abnormal heart rhythms and flushing (hot flushes).

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use DUOLIN HFA:

Always use **DUOLIN HFA** as prescribed. If you miss a dose, use **DUOLIN HFA** as soon as possible. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE-EFFECTS:

DUOLIN HFA can have side-effects.

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

Serious side-effects that you should report to your doctor as a matter of urgency include:

- Those that occur less frequently:
    - Allergic reactions, such as skin rash, swelling of the tongue, lips or face, hives or itching, and swelling of the throat with difficult breathing (see **"Take special care with DUOLIN HFA"**).
    - Unexpected constriction of the airways with wheezing or tightness of the chest (see **"Take special care with DUOLIN HFA"**).
    - Inability to pass urine with severe pain over the bladder area.
- Those for which the frequency is not known:

- Serious hypersensitivity reactions with tightness of the chest and wheezing, swelling of the face or body, hives, low blood pressure and collapse (see **"Take special care with DUOLIN HFA"**).
- Severe pain in the eye with blurred vision or halos around objects and redness of the eye (see **"Take special care with DUOLIN HFA"**).
- Chest pain with exertion that may go up to the chin or down the left arm.

Other side-effects that you should report to your doctor as soon as possible include:

- Those that occur frequently:
  - Palpitations or abnormal heart rhythm.
  - Rash or itching.
- Those for which the frequency is not known:
  - Frequent urination, excessive hunger and excessive thirst, as these symptoms may be due to high blood sugar levels.

Please report the following side-effects to your doctor or pharmacist if they continue or become bothersome:

- Those that occur frequently:
  - Nervousness, headache or dizziness.
  - Cough, throat irritation, or hoarseness.
  - Constipation or dry mouth.
  - Fine muscle tremor.
- Those that occur less frequently:
  - Nausea or vomiting.

- Muscle pain or cramps.

- Those for which the frequency is not known:
  - Redness of the feet, legs or hands due to dilation of blood vessels.
  - Poor digestion.

Please tell your doctor or pharmacist of any other undesirable effects you think may be due to **DUOLIN HFA**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF DUOLIN HFA:

Store in a cool dry place at or below 25 ℃. Avoid storage in direct sunlight or heat.

The canister is pressurised. It should not be broken, punctured or burnt, even when apparently empty.

STORE THIS MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF DUOLIN HFA:

Carton containing a pressurised aluminium container which delivers ipratropium bromide monohydrate equivalent to ipratropium 20 mcg and salbutamol sulphate equivalent to salbutamol 100 mcg in each actuation. Each container provides 200 metered dose inhalations.

IDENTIFICATION OF DUOLIN HFA:

White homogenous suspension aerosol for inhalation, in propellant HFA-227

supplied in a pressurised container.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Building 9, Parc du Cap,

Mispel Street, Bellville

7530, RSA

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