

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg, 400/12 mcg

CTD, Module 1

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

HALECORD 100/6 [INHALATION POWDER, PRE-DISPENSED 100/6 mcg]

HALECORD 200/6 [INHALATION POWDER, PRE-DISPENSED 200/6 mcg]

HALECORD 400/12 [INHALATION POWDER, PRE-DISPENSED 400/12

mcg]

budesonide/formoterol fumarate dihydrate

Contains: Sugar

100/6 mcg: lactose monohydrate 12.394 mg.

200/6 mcg: lactose monohydrate 12.294 mg

400/12 mcg: lactose monohydrate 12.088 mg

Read all this leaflet carefully before you start taking HALECORD

What is in this leaflet

1. What **HALECORD** is and what it is used for
2. What you need to know before you take **HALECORD**
3. How to take **HALECORD**
4. Possible side effects

5. How to store **HALECORD**

6. Contents of the pack and other information

1. What HALECORD is and what it is used for:

HALECORD is an inhaler that is used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 and older. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking. HALECORD contains two different medicines: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called 'corticosteroids. It works by reducing and preventing swelling and inflammation in your lungs.
- Formoterol fumarate dihydrate belongs to a group of medicines called 'long acting beta2 adrenoceptor agonists' or 'bronchodilators. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Do not use this medicine as a "reliever" inhaler

2. What you need to know before you take HALECORD:

Do not take HALECORD:

- if you are allergic to budesonide, formoterol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg. 400/12 mcg

CTD, Module 1

Take special care with **HALECORD**:

- If you are diabetic.
- If you have a lung infection.
- If you have high blood pressure or you have ever had a heart problem (including an uneven heartbeat, a fast pulse, narrowing of the arteries or heart failure).
- If you have problems with your thyroid or adrenal glands.
- If you have low levels of potassium in your blood.
- If you have severe liver problems.

Children and adolescents:

HALECORD is not recommended for children and adolescents under 18 years.

Other medicines and HALECORD:

Always tell your health care provider if you are taking any other medicines. This includes all complementary or traditional medicines.

Tell your doctor if you are taking the following medicines, before starting to use

HALECORD:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).
- Medicines for a fast or uneven heartbeat (such as quinidine).
- Medicines like digoxin, often used to treat heart failure.

Applicant/PHCR: *Innovata Pharmaceuticals (Pty) Ltd*

Product Proprietary Name: *HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.*

Dosage Form & Strength: *Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg. 400/12 mcg*

CTD, Module 1

- Diuretics, also known as ‘water tablets’ (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat COPD or asthma.
- Other bronchodilators (such as salbutamol).
- Tricyclic anti-depressants (such as amitriptyline) and the anti-depressant nefazodone.
- Phenothiazine medicines (such as chlorpromazine and prochlorperazine).
- Medicines called ‘HIV-protease inhibitors’ (such as ritonavir) to treat HIV infection.
- Medicines to treat infections (such as ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin and telithromycin).
- Medicines for Parkinson’s disease (such as leva-dopa).
- Medicines for thyroid problems (such as levo-thyroxine).

HALECORD with food, drink, and alcohol:

HALECORD can be administered irrespective of whether food is taken or not.

Pregnancy and breastfeeding and fertility:

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg. 400/12 mcg
CTD, Module 1

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines:

HALECORD has no or negligible effect on your ability to drive or to use tools or machines.

It is not always possible to predict to what extent **HALECORD** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **HALECORD** affects them.

HALECORD contains:

Sugar (Lactose monohydrate)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use HALECORD:

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

Always take **HALECORD** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

2 inhalations twice a day. Symbicort is not recommended for children or adolescents under 18 years of age.

If you have been taking steroid tablets for your COPD, your doctor may reduce the number of tablets that you take, once you start to use Symbicort. If you have been taking oral steroid tablets for a long time, your doctor may want you to have blood tests from time to time. When reducing oral steroid tablets, you may feel generally unwell even though your chest symptoms may be improving. You might experience symptoms such as a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomiting (being sick) occur, please contact your doctor immediately. You may need to take other medication if you develop allergic or arthritic symptoms. You should speak to your doctor if you are concerned as to whether you should continue to use **HALECORD**.

Important information about your COPD symptoms

If you feel you are getting breathless or wheezy while using **HALECORD**, you should continue to use **HALECORD** but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- Your breathing is getting worse or you often wake up at night feeling breathless.

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

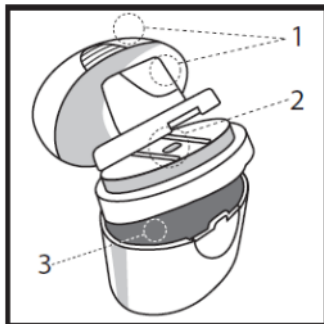
Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg, 400/12 mcg

CTD, Module 1

- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.
- These signs could mean that your COPD is not being properly controlled and you may need different or additional treatment immediately.

INSTRUCTIONS FOR USE OF THE HALECORD

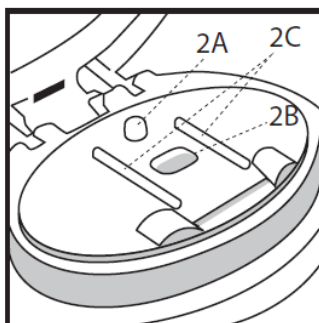
HALECORD is a device for the intake of powder for inhalation in doses. Each dose is stored in the blister of a specially designed single dose blister strip.



HALECORD device is comprised of 3 parts:

- The mouthpiece and its cap (1).
- The surface (2) on which the blister strip is placed (medicine supporting surface).
- The storage case (3) which houses the blister strips.

The three parts are connected to each other and can be opened separately.



Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

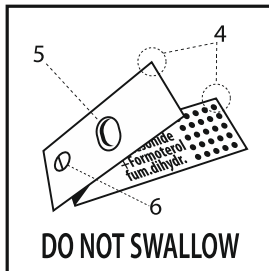
Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg, 400/12 mcg

CTD, Module 1

The medicine supporting surface contains:

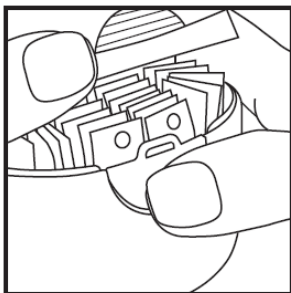
- An attachment point **(2A)** where the blister strip is attached.
- A cavity **(2B)** which accommodates the blister of the strip.
- Two strip guides **(2C)** which firmly secure the blister strip in the correct position on the medicine supporting surface.



The blister strip consists of:

- Two aluminium sheets **(4)**.
- A blister **(5)**, containing the medicine.
- A hole **(6)**.

A. Preparing the device



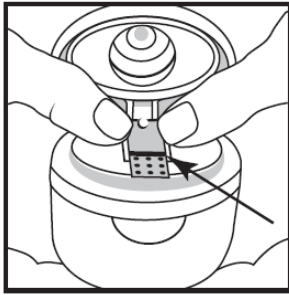
Open the storage case by pressing as in the figure, take a strip and close the storage case again.

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg, 400/12 mcg

CTD, Module 1



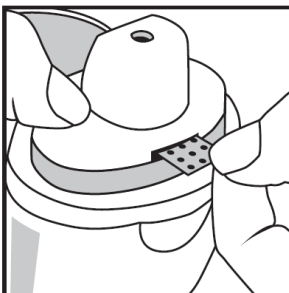
Uncover the mouthpiece completely by applying light pressure on the striped area.

Unlock and push the mouthpiece backwards so as to reveal the medicine supporting surface.

Hold the blister strip with its shiny surface upwards, so as to see the blue line, as shown by the arrow in the figure. The labeled surface of the strip should face downwards.

Place the hole of the strip on the attachment point of the drug supporting surface. By applying light pressure make sure that the strip is securely attached on the attachment point.

The blister of the strip will fit in the cavity of the drug supporting surface and the guides will secure the strip in the correct position.



Close the mouthpiece and pull away horizontally the embossed protruding end of the strip to be detached.

The dose is now ready to be inhaled.

B. Inhalation of the dose

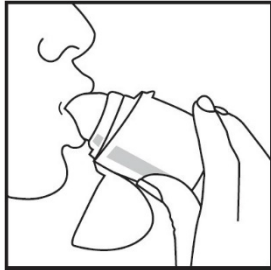
Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg, 400/12 mcg

CTD, Module 1

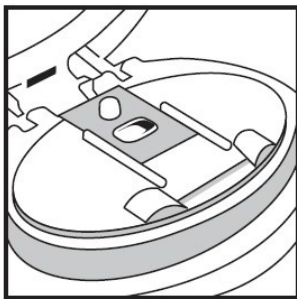
Hold the device away from your mouth. Exhale completely. Be careful not to exhale on the mouthpiece of the device. Bring **HALECORD** to your mouth and place your lips tightly around the mouthpiece.



Breathe in slowly and deeply through your mouth (and not through your nose) until your lungs are full.

Hold in your breath approximately 5 seconds or as long as you comfortably can and at the same time remove the device from your mouth.

Exhale and continue to breathe normally.



Open the mouthpiece.

You will notice that you have inhaled all the powder and that the blister of the strip is empty.

Remove the empty strip, and proceed to step C.

C. Cleaning the device

Applicant/PHCR: *Innovata Pharmaceuticals (Pty) Ltd*

Product Proprietary Name: *HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.*

Dosage Form & Strength: *Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg. 400/12 mcg*

CTD, Module 1

Following each use, wipe the mouthpiece and the drug supporting surface with a dry cloth or dry paper tissue. Do not use water to clean the device.

Close the mouthpiece and its cap.

Cleaning your inhaler

Wipe the mouthpiece of the Accuhaler with a dry tissue to clean it.

If you take more HALECORD than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of HALECORD:

Do not take a double dose to make up for forgotten individual doses.

If you stop taking HALECORD:

Before you stop using **HALECORD**, you should talk to your doctor or your pharmacist. If you stop using **HALECORD** the signs and symptoms of COPD may worsen.

4. Possible side effects

HALECORD can have side effects.

Not all side effects reported for **HALECORD** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **HALECORD**, please consult your health care provider for advice.

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg, 400/12 mcg

CTD, Module 1

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow) rash or hives together with difficulties to breathe (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction.
- Sudden acute wheezing or shortness of breath immediately after using your inhaler. If either of these symptoms occurs, stop using your **HALECORD** straightaway and use your 'reliever' inhaler. Contact your doctor immediately as you may need to have your treatment changed.

These are all profoundly serious side effects. If you have them, you may have had a serious reaction to **HALECORD**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use **HALECORD**.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your **HALECORD**.
- Mild sore throat, coughing and a hoarse voice.
- Headache.

Applicant/PHCR: *Innovata Pharmaceuticals (Pty) Ltd*

Product Proprietary Name: *HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.*

Dosage Form & Strength: *Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg. 400/12 mcg*

CTD, Module 1

- Pneumonia (infection of the lung) in COPD patients.

Tell your doctor if you have any of the following while taking **HALECORD**, they could be symptoms of a lung infection:

- Fever or chills.
- Increased mucus production change in mucus colour.
- Increased cough or increased breathing difficulties.

Less frequent side effects:

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heartbeat.
- Bruising of the skin.
- Muscle cramps.
- Blurred vision.
- Rash, itching.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using Symbicort stop using **HALECORD** and talk to your doctor immediately.
- Low levels of potassium in your blood.

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.

Dosage Form & Strength: Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg, 400/12 mcg

CTD, Module 1

- Uneven heartbeat.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse drug Reaction reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **HALECORD**.

5. How to store HALECORD

HALECORD should be stored in the original packaging (keep blisters in the carton until required for use).

Store at or below 30 °C.

Protect from moisture and sunlight.

STORE ALL MEDICINE OUT OF REACH 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

(e.g., toilets).

6. Contents of the pack and other information

What HALECORD contains:

The active substance in **HALECORD** is budesonide and formoterol fumarate dihydrate.

HALECORD 100/6 [INHALATION POWDER, PRE-DISPENSED 100/6 mcg]

100/6 microgram: Each single dose blister strip contains 100 micrograms of budesonide and 6 micrograms of formoterol fumarate dihydrate, which corresponds to an inhaled dose of 97 micrograms budesonide and 5.5 micrograms formoterol fumarate dihydrate.

HALECORD 200/6 [INHALATION POWDER, PRE-DISPENSED 200/6 mcg]

200/6 microgram: Each single dose blister strip contains 200 micrograms of budesonide and 6 micrograms of formoterol fumarate dihydrate, which corresponds to an inhaled dose of 194 micrograms budesonide and 5.5 micrograms formoterol fumarate dihydrate.

HALECORD 400/12 [INHALATION POWDER, PRE-DISPENSED 400/12 mcg]

400/12 microgram: Each single dose blister strip contains 400 micrograms of budesonide and 12 micrograms of formoterol fumarate dihydrate, which corresponds

Applicant/PHCR: *Innovata Pharmaceuticals (Pty) Ltd*

Product Proprietary Name: *HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.*

Dosage Form & Strength: *Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg. 400/12 mcg*
CTD, Module 1

to an inhaled dose of 380 micrograms budesonide and 11 micrograms formoterol fumarate dihydrate.

HALECORD contains: Sugar (Lactose monohydrate) contains milk proteins.

What HALECORD looks like and contents of the pack

HALECORD 100/6, HALECORD 200/6 and HALECORD 400.12 :

Budesonide and formoterol fumarate dihydrate 100/6 mcg:

A white plastic inhalation device, containing 60 alu-alu single dose blister strips and a spare canister containing 60 alu-alu blisters, are packed in a carton box together with the instruction leaflet (BT x 120 doses: 1 device x 60 doses + 1 canister x 60 doses)

Budesonide and formoterol fumarate dihydrate 200/6 mcg:

A white plastic inhalation device, containing 60 alu-alu single dose blister strips and spare plastic canister containing 60 alu-alu single dose blister strips packed in a carton box together with the instruction leaflet (BT x 120 doses: 1 device x 60 doses + 1 canister x 60 doses).

Budesonide & formoterol fumarate dehydrate 400/12 mcg:

A white plastic inhalation device, containing 60 alu-alu dose blister strips, packed in a carton box together with the instruction leaflet (BT x 60 doses: 1 device x 60 doses).

Applicant/PHCR: *Innovata Pharmaceuticals (Pty) Ltd*

Product Proprietary Name: *HALECORD 100/6, HALECORD 200/6 and HALECORD 400/12.*

Dosage Form & Strength: *Inhalation Powder, pre-dispensed 100/6 mcg, 200/6 mcg. 400/12 mcg*

CTD, Module 1

Holder of Certificate of Registration

Innovata Pharmaceuticals

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

This leaflet was revised in

New

Registration number

TBI

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **HALECORD**.