

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

FACET® TURBUHALER® 80:4,5 µg/dose Inhaler

FACET® TURBUHALER® 160:4,5 µg/dose Inhaler

Budesonide and formoterol fumarate dihydrate (hereafter referred to as formoterol)

Contains sugar:

FACET TURBUHALER 80:4,5 µg/dose: 810 µg lactose monohydrate per dose

FACET TURBUHALER 160:4,5 µg/dose: 730 µg lactose monohydrate per dose

Read all of this leaflet carefully before you start using FACET TURBUHALER

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FACET TURBUHALER 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.

What is in this leaflet

1. What FACET TURBUHALER is and what it is used for
2. What you need to know before you take FACET TURBUHALER
3. How to take FACET TURBUHALER
4. Possible side effects
5. How to store FACET TURBUHALER
6. Contents of the pack and other information

1 What FACET TURBUHALER is and what it is used for

FACET TURBUHALER contains an inhalation powder. The powder is a mixture of the medicines budesonide and formoterol which have different ways of treating your disease (asthma or Chronic Obstructive Pulmonary Disease [COPD]). Asthma and COPD are caused by a type of chronic inflammation in the airways. Budesonide reduces and prevents this inflammation. Formoterol widens your airways and makes it easier for you to breathe. You should notice this within 1-3 minutes after you have inhaled the medicine and the effect lasts for up to 12 hours.

When you breathe in through the mouthpiece of the inhaler, the medicine follows your breath to your lungs (see “Instructions for use” at the end of this leaflet).

2 What you need to know before you use FACET TURBUHALER

Do not use FACET TURBUHALER:

- If you are hypersensitive (allergic) to budesonide or formoterol or any of the other ingredients of FACET TURBUHALER (listed in section 6).
- FACET TURBUHALER should not be used in children below the age of 12 years.

Warnings and precautions

Take special care with FACET TURBUHALER:

- if you currently have or have had, a heart disorder such as irregular heartbeat, high blood sugar (diabetes mellitus), problems with your thyroid (thyrotoxicosis) or low potassium in your blood (hypokalaemia).
- if you use FACET TURBUHALER to treat your COPD and you have any of the following symptoms, which could be signs of pneumonia (infection of the lung): fever or

chills, increased mucus production or change in mucus colour, increased cough or increased breathing difficulties.

- if you are already taking any other medicines including those you have bought without a prescription.
- if you are already taking medicines for allergy, high blood pressure, heart conditions, fungal infections, depression and also some types eye drops.

FACET TURBUHALER has been prescribed for your airway disease (asthma or COPD).

Never lend your FACET TURBUHALER to someone else.

Other medicines and FACET TURBUHALER

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

- If you are taking ketoconazole (medicine for fungal infections) for longer than 2 weeks, it can increase the amount of the budesonide component of FACET TURBUHALER in the body.
- Quinidine, disopyramide, procainamide, phenothiazines, Antihistamines, monoamine oxidase inhibitors and tricyclic antidepressants can increase the risk of irregular heartbeat.
- Some medicines for high blood pressure, heart conditions, fungal infections, depression and some eye drops may alter the effect of FACET TURBUHALER if you use them at the same time.

Pregnancy and breastfeeding

Before you start using FACET TURBUHALER, tell your doctor if you are pregnant, trying to become pregnant or if you are breastfeeding.

If you become pregnant while using FACET TURBUHALER, you should tell your doctor as soon as possible. You should not stop taking the medicine without discussing this with your doctor.

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 professional for advice before using FACET TURBUHALER.

Women who are using FACET TURBUHALER should not breastfeed their babies.

Driving and using machines

FACET TURBUHALER is not expected to affect your ability to drive or to operate any tools or machines.

FACET TURBUHALER contains lactose monohydrate (sugar)

FACET TURBUHALER contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not use FACET TURBUHALER. The lactose may contain milk protein.

3 How to use FACET TURBUHALER

- Do not share medicines prescribed for you with any other person.
- Always use FACET TURBUHALER exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.
- Before you start using FACET TURBUHALER for the first time, it is important that you read the information “Instructions for use” at the end of this leaflet and follow the instructions carefully.

- The dosage of FACET TURBUHALER is individual. If you use FACET TURBUHALER as a maintenance therapy, the maintenance dose should be taken even when you have no symptoms. Your doctor will adjust your medicine to the lowest dose that controls your asthma or COPD. Follow your doctor's directions carefully. The directions may be different from the information contained in this leaflet.
- If you have the impression that the effect of FACET TURBUHALER is too strong or too weak, tell your doctor or pharmacist.
- Do not increase the dose of FACET TURBUHALER without talking to your doctor.
- **Remember:** Rinse your mouth out with water after taking your regular morning and/or evening dose for your asthma or COPD. If you use FACET TURBUHALER for your asthma, you do not have to rinse your mouth if you have used reliever doses for your symptoms.
- Do not adjust or stop the dose without talking to your doctor first. If you are instructed by your doctor to discontinue treatment with FACET TURBUHALER, follow any directions on dose reduction carefully.

If you use more FACET TURBUHALER than you should

It is **important** to use only the number of puffs your doctor has prescribed. If you use more than the recommended dose you will increase the risk of side effects.

The most common symptoms and signs that may occur after overdose are: trembling, headache and rapid heartbeat.

If you use too much FACET TURBUHALER over a longer period (months), it is possible that you may get side effects related to budesonide. If you think this may have happened to

you or if any of the above-mentioned symptoms bother you, please discuss it with your doctor.

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

If you forget to use FACET TURBUHALER

If you forget to take a maintenance dose of FACET TURBUHALER it is not necessary to compensate for the dose you missed. Just take the next dose as prescribed.

4 Possible side effects

FACET TURBUHALER can have side effects.

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

Contact your doctor if any of the following side effects bother you or if any other unusual effects bother you.

Frequent side effects:

- Irritation in the throat, coughing, hoarseness, thrush (fungal infection in the mouth and throat)
- headache
- trembling
- rapid heartbeat

- pneumonia in COPD patients

Less frequent side effects:

- sleep difficulties, restlessness and nervousness
- dizziness
- nausea
- muscle cramps and agitation
- skin rash
- itching
- spasm in the airways
- irregular heartbeats
- skin bruising
- severe allergic reactions
- high blood sugar levels
- facial swelling
- depression
- behavioural disturbances
- chest pain

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 FACET TURBUHALER.

5 How to store FACET TURBUHALER

Store all medicines out of reach of children.

Store at or below 30 °C.

Always replace the mouthpiece cover after using FACET TURBUHALER.

Do not use FACET TURBUHALER after the shelf-life expiry date.

Return all unused medicine to your pharmacist. Always be sure to dispose of your used FACET TURBUHALER responsibly, since some of the medicine will remain inside it. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6 Contents of the pack and other information

What FACET TURBUHALER contains

- The active substances in FACET TURBUHALER 80:4,5 µg/dose are budesonide 80 micrograms and formoterol 4,5 micrograms/inhalation.
- The active substances in FACET TURBUHALER 160:4,5 µg/dose are budesonide 160 micrograms and formoterol 4,5 micrograms/inhalation.
- The other ingredient is lactose monohydrate.

What FACET TURBUHALER looks like and contents of the pack

FACET TURBUHALER is a multidose inspiratory flow driven, dry powder inhaler. The inhaler is made of plastic parts. Each inhaler contains 60 doses or 120 doses.

Inhaler:

The colour of the turning grip is red. On the turning grip a Braille code is embossed. The colour of the cover is white. Inside the cover 5 fins are present. The figure 60 or 120 is visible in the dose-indicator window.

The mouthpiece has 4 bars, and can be rotated.

Contents:

The contents are white to off-white, predominantly in the form of rounded granules.

Holder of certificate of registration

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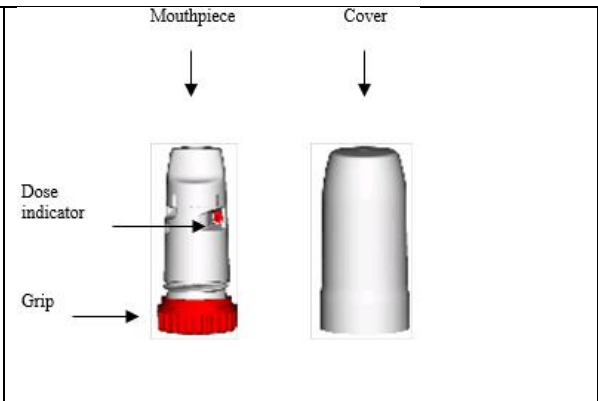
FACET TURBUHALER 80:4,5 µg/dose: 45/21.5.1/0257

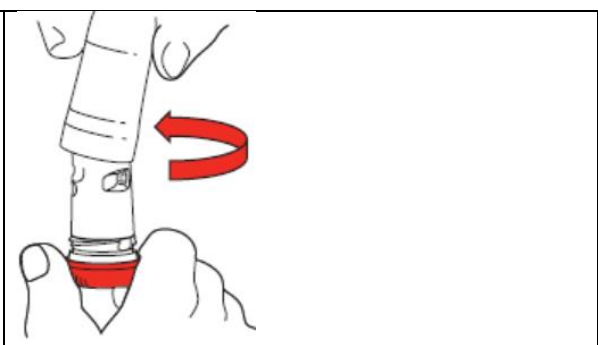
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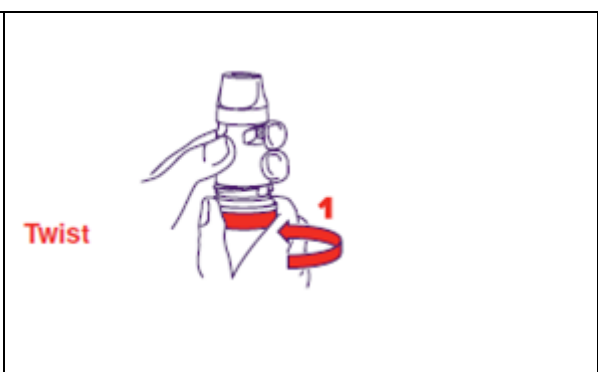
INSTRUCTIONS FOR USE/HANDLING:

Please read the complete instructions carefully before you start to take your medication.

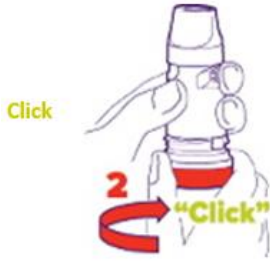
Turbuhaler (Fig.1) is a multidose inhaler from which very	
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<p>small amounts of powder (which you will not taste or feel) are administered. When you breathe in through Turbuhaler the powder is delivered to your lungs. It is therefore important that you inhale forcefully and deeply through the mouthpiece.</p>	 <p>The diagram shows two views of the Turbuhaler device. On the left, the device is shown with the mouthpiece and cover removed. Labels with arrows point to the 'Mouthpiece' at the top, the 'Cover' at the bottom, the 'Dose indicator' (a red window showing a white mark), and the 'Grip' (a red base). On the right, the 'Cover' is shown separately. Below the diagrams is the caption 'Fig.1'.</p>
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<p>How to use Facet Turbuhaler</p> <p>To administer one dose, simply follow the instructions below.</p> <p>Unscrew and lift off the cover (Fig.2).</p>	 <p>The diagram shows a hand holding the Turbuhaler device. A red curved arrow indicates the direction to unscrew the cover. Below the diagram is the caption 'Fig.2'.</p>
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<p>TWIST, CLICK AND INHALE</p> <p>1. TWIST</p> <p>Hold the inhaler upright with the red grip downwards and twist the grip as far as it will go in one direction. It does not matter which way you turn first. Do not hold the mouthpiece when you turn the grip (Fig. 3).</p>	 <p>The diagram shows a hand holding the Turbuhaler device. A red curved arrow labeled '1' indicates the direction to twist the grip. The word 'Twist' is written in red next to the arrow. Below the diagram is the caption 'Fig.3'.</p>
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<p>2. CLICK</p> <p>Then twist the grip as far as it will go in the opposite direction (Fig. 4).</p>	
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<p>A click will tell you that your dose is loaded.</p> <p><i>Perform the procedure twice if you are using the Turbuhaler for the first time.</i></p> <p>Breathe out. Do not breathe out through the mouthpiece.</p>	 <p>Fig. 4</p>
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<p>3. INHALE</p> <p>Place the mouthpiece gently between your teeth, close your lips and inhale forcefully and deeply through the device. Do not chew or bite hard on the mouthpiece.</p>	 <p>Fig.5</p>
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Remove the inhaler from your mouth, before breathing out.

If more than one dose has been prescribed, repeat steps 1-3.

REMEMBER YOU WILL NOT TASTE OR FEEL THE POWDER.

Replace the cover (by screwing it back on tightly) after use.

Rinse your mouth with water after the daily maintenance dose. Do not swallow.

Cleaning:

Wipe the outside of the mouthpiece regularly (once a week) with a dry tissue. Do not use water or other liquids when cleaning the mouthpiece.

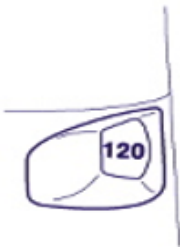
IMPORTANT INFORMATION TO NOTE:

Don't be concerned if you click your Turbuhaler more than once. The dose counter will continue moving, however it can only give you one dose at a time.

Do not try to remove the mouthpiece since it is fixed to the inhaler. The mouthpiece can be rotated, but do not twist it unnecessarily.

As the amount of powder dispensed is very small, you may not be able to taste it after inhalation. However, you can still be confident that you have inhaled the dose if you have followed the instructions.

The rattling sound heard if you shake the inhaler is not produced by the medication but by the drying agent.

<p>How will I know when to replace my inhaler?</p> <p>The dose indicator (Fig. 6) tells you approximately how many doses are left in the inhaler, starting with either 60 or 120 when full.</p> <p>The indicator is marked in intervals of 10 doses. Therefore it does not show the loading of each individual dose.</p> <p>You should be reassured that Turbuhaler delivers the dose even if you may not notice a movement in the dose indicator.</p>	 <p>Fig. 6</p>
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For the last 10 doses, the background of the indicator is red. When the zero reaches the middle of the window (Fig. 7), it is time for you to discard the inhaler.

Please note that even when the dose indicator registers zero, it is still possible to turn the grip. The red grip will still twist and click even when your Turbuhaler is empty.

However, the indicator stops moving and the zero remains in the window.

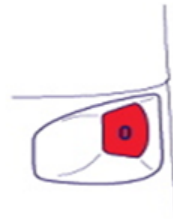


Fig.7