

**Patient Package Insert in Accordance With**  
**the Pharmacists' Regulations (Preparations) – 1986**

The medicine is dispensed with a doctor's prescription only

## **Symbicort® Turbuhaler® 160/4.5 mcg/dose**

### **Inhalation powder**

Each inhalation contains:

Budesonide micronized	160 micrograms
Formoterol fumarate dihydrate	4.5 micrograms

For inactive ingredients, please refer to Section 6 - "Further Information". See also "Important information about some of the ingredients in this medicine" in section 2.

Each inhaler contains either 60 or 120 inhalations.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet; you may need it again.  
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

The medicine is not intended for children and adolescents below the age of 12.

The treatment with Symbicort Turbuhaler 160/4.5 mcg/dose for patients who have chronic obstructive pulmonary disease (COPD) is only intended for adult patients (aged 18 years and older).

### **1. WHAT IS THIS MEDICINE INTENDED FOR?**

Symbicort Turbuhaler 160/4.5 mcg/dose is an inhaler that is used to treat asthma in adults and adolescents aged 12–17 years.

This medicine is also used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 years and older only.

COPD is a chronic disease characterized by constant disturbance of airflow into and out of the lungs, which is often caused by cigarette smoking.

### **Therapeutic group**

Budesonide - this medicine belongs to a group of medicines called - corticosteroids. It works by reducing and preventing swelling and inflammation in your lungs. Formoterol fumarate dihydrate – this medicine belongs to a group called beta-2 agonist/bronchodilator. It works by relaxing the muscles in your airways and have a prolonged activity.

## **2. BEFORE USING THE MEDICINE**

### **Do not use this medicine if:**

You are sensitive (allergic) to the active ingredients or to the inactive ingredient (see section 6), which is lactose (which contains small amounts of milk protein).

**Special warnings regarding use of Symbicort Turbuhaler 160/4.5 mcg/dose:**

**Important information regarding symptoms of COPD and asthma:**

If you experience shortness of breath or wheezing while using Symbicort Turbuhaler; continue taking the medicine and refer to a doctor as soon as possible, you may need an additional treatment.

**Refer to the doctor immediately in the following cases:**

- If you experience worsening of your breathing difficulties or if you frequently wake up at night with asthma.
- If you experience chest tightness in the morning, or tightness lasts longer than usual.

These signs can indicate that your asthma or COPD are not under control and that you immediately need alternative or additional treatment.

**Before treatment with Symbicort Turbuhaler 160/4.5 mcg/dose, tell the doctor if:**

- you are diabetic.
- you have a lung infection.

- You have high blood pressure, you have or have ever had a heart problem (including irregular heartbeat, a very fast pulse, narrowing of the arteries or heart failure).
- You have problems with your thyroid or adrenal glands.
- you have low levels of potassium in the blood.
- you have severe liver problems.

Contact your doctor if you experience blurred vision or other visual disturbances.

#### **If you are taking other medicines**

**If you are taking, or if you have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

Especially if you are taking:

- medicines from the beta blockers group (such as atenolol, propranolol for high blood pressure), including eye drops (such as timolol for treatment of glaucoma).
- antidepressants from the tricyclics group (such as amitriptyline), and antidepressants such as nefazodone.
- phenothiazines (such as chlorpromazine and prochlorperazine).
- medicines for treating fast or irregular heartbeat (such as quinidine), or heart failure (such as digoxin).
- oral steroids (such as prednisolone).
- xanthine derivatives (such as aminophylline or theophylline), these are often used to treat asthma
- medicines called 'HIV-protease inhibitors' (such as ritonavir) to treat HIV infection.
- medicines to treat infections (such as itraconazole, ketoconazole, voriconazole, posaconazole, clarithromycin and telithromycin).
- diuretics (such as furosemide) to treat high blood pressure.
- bronchodilators (such as salbutamol)
- medicines to treat Parkinson's disease (such as levodopa)

- medicines for thyroid problems (such as levothyroxin).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Symbicort Turbohaler. In addition, tell the doctor if you are planning to undergo surgery or dental treatment that requires general anesthesia.

### Pregnancy and breastfeeding

- If you are pregnant or are considering becoming pregnant, consult the doctor before using Symbicort Turbuhaler 160/4.5 mcg/dose - Do not use the medicine unless instructed to do so by the doctor.
- If you become pregnant while using Symbicort Turbuhaler 160/4.5 mcg/dose, do not stop treatment, however, contact the doctor immediately.
- If you are breastfeeding, consult the doctor before using the medicine.

### Driving and using machinery

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

### Important information about some of the ingredients in this medicine

Symbicort Turbuhaler 160/4.5 mcg/dose contains lactose, which is a type of sugar. If your doctor has told you that you have an intolerance to some sugars, consult the doctor before taking this medicine. The amount of lactose in this medicine does not normally cause problems in patients with lactose intolerance. Lactose, the inactive ingredient in the medicine, contains a small amount of milk proteins, which can cause an allergic reaction.

## 3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
- It is important to use Symbicort Turbuhaler every day, regardless to the appearance of asthma or COPD symptoms.

- If you are using this medicine to treat asthma, the attending doctor may regularly monitor your symptoms.
- **Do not exceed the recommended dose.**

If you are taking tablets containing steroids to treat asthma or COPD, the attending doctor may prescribe a decrease in the number of tablets you are taking when you start using Symbicort Turbuhaler 160/4.5 mcg/dose; if you have been taking steroid tablets for a long period, the attending doctor may order to perform blood test. When reducing the dose of oral steroid tablets, you may feel generally unwell even though your respiratory symptoms may be improving. You might experience any of the following symptoms: stuffy or runny nose, weakness or pain in joints or muscles and skin rash (eczema). If any of these symptoms bother you, or if you experience headache, tiredness, nausea or vomiting, report to the doctor immediately. You may need to take other medicine if you develop an allergy or symptoms of arthritis. You should contact the doctor if you are not sure whether you should continue to use Symbicort Turbuhaler 160/4.5 mcg/dose in this case.

The doctor may consider adding steroid tablets to your Symbicort Turbuhaler 160/4.5 mcg/dose treatment plan, particularly during stressful periods (for instance if you have a chest infection or before surgery).

Dosage and manner of treatment will be determined only by the doctor. The recommended dosage is usually:

### **Dosage for treating Asthma**

Symbicort Turbuhaler 160/4.5 mcg/dose can be prescribed for asthma in two different ways. The manner of treatment of Symbicort Turbuhaler 160/4.5 mcg/dose the amount and the frequency depends on how it has been prescribed for you:

- **You may be prescribed Symbicort Turbuhaler and a separate reliever inhaler.** In this case you should use the separate reliever inhaler if you get an asthma attack. See the “Asthma 1” section.
- **Symbicort Turbuhaler may be prescribed as your only inhaler.** In this case you do not need a supplementary inhaler: Symbicort acts rapidly as a reliever. See

the “Asthma 2” section.

### Asthma 1

Using Symbicort Turbuhaler 160/4.5 mcg/dose and a separate supplementary reliever inhaler:

- **Use your Symbicort Turbuhaler every day to prevent asthma symptoms from happening.**
- **Use a separate supplementary reliever inhaler when you need to treat asthma attacks.**

	<b>Adults (age 18 and above)</b>	<b>Adolescents (age 12-17)</b>	<b>Children (age 6-11)</b>
<b>Symbicort Turbuhaler 160/4.5 mcg/dose</b>	<b>1-2 inhalations, twice a day.</b>  The doctor may increase the dosage to 4 inhalations, twice a day.  If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.	<b>1-2 inhalations, twice a day.</b>  If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.	<b>Symbicort Turbuhaler 160/4.5 mcg/dose is not intend for use in children.</b>  Only the 80/4.5 strength is used for children.

Always keep your supplementary reliever inhaler with you to use when you need it.

Do not use Symbicort Turbuhaler to treat asthma symptoms - use only your supplementary reliever inhaler.

### Asthma 2

If your doctor has told you to use only Symbicort Turbuhaler 160/4.5 mcg/dose without other inhalers, and you are aged 12 and above, this is how to use it:

- **Use your Symbicort Turbuhaler every day to prevent asthma symptoms from happening.**
- **Use your Symbicort Turbuhaler when you need to treat asthma attacks.**

**Using Symbicort Turbuhaler 160/4.5 mcg/dose every day:**

	Adults	Adolescents aged 12 and above	Children under the age of 12
Symbicort Turbuhaler 160/4.5 mcg/dose	<p>1 inhalation in the morning and 1 inhalation in the evening or 2 inhalations in the morning or 2 inhalations in the evening.</p> <p>The doctor may increase this dosage to 2 inhalations twice a day.</p>	<p>1 inhalation in the morning and 1 inhalation in the evening or 2 inhalations in the morning or 2 inhalations in the evening.</p> <p>The doctor may increase this dosage to 2 inhalations twice a day.</p>	Not to be used

**Using Symbicort Turbuhaler 160/4.5 mcg/dose to treat asthma attacks, as necessary:**

	Adults	Adolescents aged 12 and above	Children under the age of 12
Symbicort Turbuhaler 160/4.5 mcg/dose	<p>If you get asthma symptoms, take 1 inhalation and wait a few minutes. If you do not feel better, you can take another inhalation.</p> <p>Do not take more than 6 inhalations at a single time.</p>	<p>If you get asthma symptoms, take 1 inhalation and wait a few minutes. If you do not feel better, you can take another inhalation.</p> <p>Do not take more than 6 inhalations at a single time.</p>	Not to be used

Always keep your supplementary reliever inhaler with you to use when you need it.

**A total daily dose of more than 8 inhalations is not normally needed. However, your doctor may allow you to take up to 12 inhalations a day for a limited period.**

If you regularly need to use 8 or more inhalations a day, it is strongly recommended that you make an appointment to see your doctor or nurse who may need to change your treatment.

Do not use more than 12 inhalations in total in 24 hours.

If you are doing exercise and you get asthma symptoms, use the inhaler as described here. However, do not use Symbicort Turbuhaler 160/4.5 mcg/dose just before exercise to stop asthma symptoms from happening.

#### **Treatment of Chronic Obstructive Pulmonary Disease (COPD)**

**For use by adults only (18 years old and above)**

Symbicort Turbuhaler 160/4.5 mcg/dose	Adults (age 18 and above)	Adolescent (age 12-17)	Children (age 6-11)
	2 inhalations, twice a day	Not to be used	Not to be used

Your doctor may add to your treatment program other bronchodilator drugs, for example anticholinergics such as – tiotropium or ipratropium bromide.

#### **Instructions for use of Symbicort Turbuhaler 160/4.5 mcg/dose**

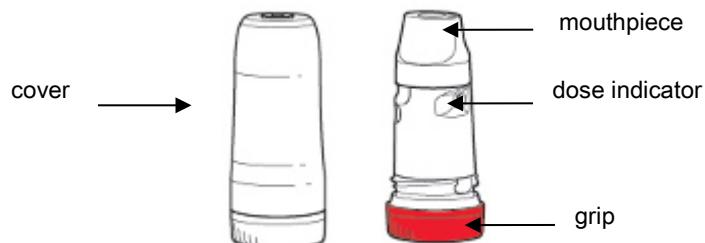


Figure 1

### How to prepare a new inhaler for use

Before using **a new Symbicort Turbuhaler 160/4.5 mcg/dose for the first time**, you need to prepare the inhaler for use as follow:

1. Unscrew the cover and lift it off. You may hear a rattling sound when you unscrew the cover.
2. Hold the inhaler upright with the red grip at the bottom (Figure 2).
3. To load the inhaler, turn the red grip as far as it will go in one direction. Then turn it back as far as it will go in the other direction. It does not matter which way you turn it first. You will hear a click during this procedure. It does not matter whether the click comes on the first or the second twist.
4. Repeat this procedure twice, turning the red grip in both directions.
5. The inhaler is now loaded and ready for use.

### How to take an inhalation

Every time you need to take an inhalation, follow the instructions below:

1. Unscrew the cover and lift it off. You may hear a rattling sound when you unscrew the cover.
2. Hold the inhaler upright with the red grip at the bottom (Figure 2).
3. Do not hold the mouthpiece when you turn the grip. To load the inhaler with a dose, **turn the grip as far as it will go in one direction and then turn it as far as it will go in the other direction**. It does not matter which way you turn it first. You will hear a click during this procedure. It does not matter whether the click comes on the first or the second twist. Your inhaler is now loaded and ready to use. Only load your inhaler when you need to use it.

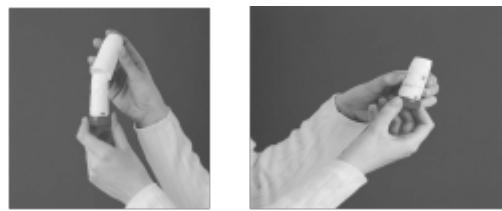


Figure 2

4. Hold your Turbuhaler away from your mouth. Breathe out gently (as far as is comfortable). Do not breathe out through the mouthpiece.
5. Gently place the mouthpiece between your teeth. Close your lips. Breathe in deeply and forcefully as much as you can through your mouth (Figure 3). Do not chew or bite the mouthpiece.



Figure 3

6. Remove the inhaler from your mouth. Then breathe out gently. Since the amount of medicine that is inhaled is very small, you may not be able to taste it after you inhale, however, if you have followed the instructions, you can be confident that you have inhaled the dose.
  7. If you have been prescribed more than one inhalation, repeat steps 2-6.
  8. After use, screw the cover on back tightly.
  9. After each use in the morning and/or in the evening, rinse your mouth with water and spit it out.
- Do not try to remove or twist the mouthpiece. It is fixed to the inhaler and must not be taken off. Do not use your Turbuhaler if it is damaged or if the mouthpiece has come off the inhaler.
  - As with all inhalers, caregivers should ensure that children use correct inhalation technique, as described above.

## Cleaning

Clean the outside of the mouthpiece regularly (once a week) with a dry tissue.

**Do not use water or other liquids to clean the mouthpiece.**

### How do I know when to replace the inhaler?

- The dose indicator (Figure 4) shows how many doses remain in the inhaler, starting with 120 or 60 when the inhaler is full.
- The dose indicator is marked in 10-dose intervals so it does not show every dose that is loaded.
- When you first see a red mark at the edge of the indicator window, there are approximately 20 doses left. For the last 10 doses, the background of the dose indicator is red. When the '0' has reached the middle of the window (Figure 5), you must start using new Symbicort Turbuhaler.

Note!

Even when the inhaler is empty, you can still twist the grip and hear a click;



Figure 4

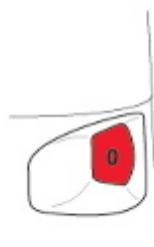


Figure 5

- The sound that you hear as you shake the inhaler is produced by a drying agent and not the medicine. Therefore, the sound does not tell you how much medicine is left in the inhaler.
- If you load your Turbuhaler more than once by mistake before taking your dose, you will still only receive one dose. However, the dose indicator will register all the loaded doses.

This medicine should be used at regular intervals, according to the dosage prescribed by the attending doctor and as stated on the pharmacist label, for the

treatment of asthma and COPD. You should not exceed your prescribed dose without seeking medical advice first.

**If you accidentally take too high a dosage**

you might experience any of the following symptoms: tremor, headache or palpitations. If you accidentally took an overdose, or if a child has accidentally used the medicine, immediately refer to a hospital emergency room and bring the medicine package with you.

**If you forgot to take a Symbicort Turbuhaler dose**

take the dose as soon as you remember. However, if the next scheduled dose is due shortly, skip the missed dose. Do not take a double dose to compensate for a missed one.

**Do not take medicines at the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.**

**If you have any further questions regarding use of the medicine, consult the doctor or the pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, use of Symbicort Turbuhaler may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

**Stop using Symbicort Turbuhaler 160/4.5 mcg/dose and refer to the doctor immediately if:**

- you experience swelling of the face particularly around the mouth (tongue and/or throat and/or difficulty swallowing), rash or hives (urticaria) with difficulty breathing (angioedema) and/or sudden feeling of faintness. These effects could indicate that you are having an allergic reaction. These effects are rare and affects less than 1 in 1,000 patients.

- you experience sudden and acute wheezing or shortness of breath immediately after using the inhaler. If any of these symptoms appears, stop taking Symbicort Turbuhaler immediately and use the relief inhaler. Contact the attending doctor immediately because you may need to have your treatment changed. These effects are very rare and affects less than 1 in 10,000 patients.

Additional side effects:

**Very common side effects (may affect up to 1 in 10 patients):**

- Palpitations (feeling your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue the treatment.
- Mouth sores (oral thrush). This is less likely if you rinse your mouth out with water every time after you finish using the inhaler.
- Mild sore throat, coughing and a hoarse voice.
- Headache.
- Pneumonia in COPD patients.

Tell your doctor if you have any of the following effects, they could be symptoms of pneumonia:

Fever or chills, increased mucus production or change in mucus color, worsening of cough or of breathing difficulties.

**Common side effects (may affect up to 1 in 100 patients):**

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heart beat.
- Bruising of the skin.

- Muscle cramps.
- Blurred vision.

**Rare side effects (may affect up to 1 in 1,000 patients):**

- Rash and itching.
- Low levels of potassium in the blood.
- Irregular heart rate.
- Bronchospasm (narrowing of the airways which causes wheezing). If wheezing appears suddenly after using the Symbicort Turbuhaler, stop using the inhaler and contact the doctor immediately.

**Very rare side effects (may affect up to 1 in 10,000 patients):**

- Depression.
- Behavioral disturbances, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- Increase in blood sugar (glucose) level.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in blood pressure.

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. This effect includes:

- Changes in bone density (thinning of the bones).
- Cataract (clouding of the lens of the eye).
- Glaucoma (increased pressure in the eye).
- A slowing in the rate of growth of children and adolescents.
- Effect on the adrenal gland (a small gland next to the kidney).

These effects are less likely to happen with inhaled corticosteroids than with oral corticosteroids (such as tablets).

If any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

## **5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Keep the inhaler cap tightly closed after use.
- Do not store above 30°C.
- Discard the inhaler after you have used the last dose; do not throw it away via household waste. Consult your pharmacist how to throw away the inhaler.

## **6. FURTHER INFORMATION**

In addition to the active ingredients, the medicine also contains:

Lactose monohydrate (which contains milk proteins) - 730 mcg/dose.

What does the medicine look like and what are the contents of the package:  
Symbicort Turbuhaler 160/4.5 mcg/dose is an inhaler containing your medicine. The inhaled powder is white in color. Each Turbuhaler contains 60 or 120 doses. The inhaler body is white with a red grip. The grip has a Braille code.

**License holder and Importer:**

AstraZeneca (Israel) Ltd.,  
1 Atirei Yeda St., Kfar Saba 4464301.

**Manufacturer:**

AstraZeneca AB, Södertälje,  
Sweden.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

123 77 30317 00

Revised in May 2021 according to the MoH guidelines.