

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

**SYMBICORT® TURBUHALER® 80/4.5 mcg/dose**

Inhalation powder

Each inhalation contains:

Budesonide micronized 80 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 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.

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

For the treatment of asthma in patients where use of a combination of inhaled corticosteroid and long acting beta agonist is appropriate.

This medicine can be prescribed in different ways for different patients:

- Symbicort Turbuhaler and a supplementary inhaler – two inhalers for asthma. These patients will use a Symbicort Turbuhaler every day, and use the supplementary inhaler when they need to treat asthma attacks.
- Symbicort Turbuhaler on its own – one inhaler for asthma. These patients will use Symbicort Turbuhaler every day, and use Symbicort Turbuhaler when they need to treat asthma attacks.

**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 80/4.5 mcg/dose:**

**Before treatment with Symbicort Turbuhaler 80/4.5 mcg/dose tell your doctor if you:**

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

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

### **Children and adolescents**

The medicine is not intended for children below the age of 6.

### **Tests and follow up**

You may be taking other products which may cause hypokalemia (low potassium levels), for example diuretics (e.g. furosemide), steroids or xanthine derivatives (used for treating asthma). If this is the case, or if your doctor suspects that your potassium levels are low (for example, if your asthma is worsening), he/she may occasionally take blood samples to check the amount of potassium in your blood.

### **Drug interactions:**

**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:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).
- Medicines for a fast or irregular heart beat (such as quinidine).
- Medicines like digoxin, often used to treat heart failure.
- Diuretics (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 asthma.
- Other bronchodilators (such as salbutamol).
- Tricyclic anti-depressants (such as amitriptyline) and the anti-depressant nefazodone.
- Phenothiazine medicines (such as chlorpromazine, 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 levo-dopa).
- Medicines for thyroid problems (such as levo-thyroxine).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Symbicort Turbuhaler.

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

### **Pregnancy and breast-feeding**

- If you are pregnant, or planning to get pregnant, talk to your doctor before using Symbicort Turbuhaler 80/4.5 mcg/dose - do not use the medicine unless your doctor tells you to.
- If you get pregnant while using Symbicort Turbuhaler 80/4.5 mcg/dose, do not stop using the medicine but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using the medicine.

### **Driving and using machines**

Symbicort Turbuhaler 80/4.5 mcg/dose 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 contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

The excipient lactose contains small amounts of milk proteins, which may 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 about the dosage and manner of treatment in this medicine.
- It is important to use Symbicort Turbuhaler every day, regardless to the appearance of asthma symptoms.
- Your doctor will want to regularly check your asthma symptoms.
- **Do not exceed the recommended dose.**

If you have been taking steroid tablets for your asthma, your doctor may reduce the number of tablets that you take, once you start to use **Symbicort Turbuhaler**, and may stop your steroid tablets altogether. If you have been taking steroid tablets for a long time, your doctor may want you to have a blood test. You might experience some symptoms as a result of reducing the steroid tablets: a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema) or generally feeling unwell; if so, continue using **Symbicort Turbuhaler** and let your doctor know:

- If you have been taking steroid tablets for your asthma and have recently started taking **Symbicort Turbuhaler** and have reduced or stopped the steroid tablets, **or**
- If you have been taking inhaled steroids (e.g. **Symbicort Turbuhaler** or budesonide alone) for a long time.

The doctor may consider **adding** steroid tablets to your treatment with **Symbicort Turbuhaler**, particularly in periods of stress (for example if you have a chest infection or if you are about to undergo an operation).

In children who are treated with inhaled steroids for a long time, the doctor will monitor their height.

**Symbicort Turbuhaler** can be prescribed for asthma in two ways:

- A. **You may be prescribed Symbicort Turbuhaler and a supplementary inhaler.** In this case you should use the supplementary inhaler if you get an asthma attack. **See the “Asthma 1” section.**
- B. **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.**

**Please read the tables carefully** to make sure you use **Symbicort Turbuhaler** in the way your doctor prescribed it.

**Always use Symbicort Turbuhaler exactly as your doctor has instructed you.** The label on the box and your personal Asthma Action Plan (if you have one) will remind you. Check with your doctor, nurse or pharmacist if you are in any doubt.

**Your dose of Symbicort Turbuhaler is personal to you.** Your doctor will prescribe the lowest dose that controls your asthma.

If you have been prescribed a supplementary inhaler as well as **Symbicort Turbuhaler**, do not use Symbicort for an asthma attack. Use your supplementary inhaler.

**Contact the doctor immediately:**

- **If you are not getting relief from your current dose.**
- **If you are not getting relief from your supplementary reliever inhaler or are using it more often than usual.**
- **If your breathing is getting worse.**
- **If you often wake up at night with asthma.**
- **If your chest starts to feel tight in the morning or if tightness lasts longer than usual.**

If you feel you are getting breathless or wheezy while using **Symbicort Turbuhaler**, you should continue to use **Symbicort Turbuhaler** but go to see your doctor (or

asthma nurse) as soon as possible, as you may need additional treatment.

### Asthma 1

Has your doctor prescribed Symbicort Turbuhaler together with a supplementary reliever inhaler?

Yes, see the below table.

No, see the “Asthma 2” section.

If you were prescribed Symbicort Turbuhaler and a supplementary reliever inhaler, this is how to use them:

- Use Symbicort Turbuhaler every day.
- Use a separate supplementary reliever inhaler when you need to treat asthma attacks.

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

Symbicort Turbuhaler 80/4.5		
Adults (age 18 and above)	Adolescents (age 12-17)	Children (age 6-11)
1-2 puffs, twice a day May be increased to 4 puffs, twice a day.	1-2 puffs, twice a day.	2 puffs, twice a day.

### Asthma 2

Is Symbicort Turbuhaler your only prescribed inhaler?

If your doctor has told you to use only Symbicort Turbuhaler without other inhalers, this is how to use it:

- Use Symbicort Turbuhaler everyday.
- Use Symbicort as a reliever when you need to treat asthma attacks.

Always keep your Symbicort Turbuhaler with you to use when you need it.

Using Symbicort every day:

Symbicort Turbuhaler 80/4.5	
Adults	Adolescents and Children under 18 years of age
2 inhalations, one in the morning and one in the evening, OR	Not to be used

2 inhalations in the morning OR 2 inhalation in the evening.	
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**Using Symbicort to treat asthma attacks:**

<b>Symbicort Turbuhaler 80/4.5</b>	
<b>Adults</b>	<b>Adolescents and Children under 18 years of age</b>
<p>Take one inhalation and wait a few minutes.</p> <p>If you do not feel better, take another inhalation.</p> <p>Do not take more than 6 inhalations for each attack.</p>	<b>Not to be used</b>

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

Do not take more than 12 inhalations in 24 hours.

Do not exceed the recommended dosage.

This medicine is not intended for administration to children under 6 years of age.

This medicine is to be taken at specific time intervals as determined by the attending doctor.

**How to Use Symbicort Turbuhaler 80/4.5 mcg/dose**

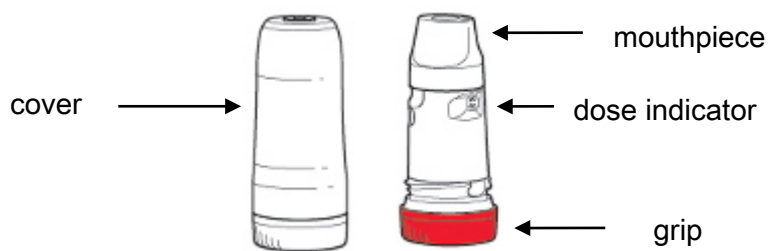


Figure 1

**How to prepare a new inhaler for use**



Before using a **new** Symbicort Turbuhaler for the first time you need to prepare the inhaler for use.

- Unscrew and lift off the cover. You may hear a rattling sound when you unscrew the cover.
- Hold the inhaler upright with the grip downwards (Figure 2).
- To load turn the red grip as far as it will go in one direction. Then turn it as far as it will go in the other direction. It does not matter which way you turn it first. You should hear a click sound. It does not matter whether the click comes on the first or the second twist.
- Do this again, turning the red grip in both directions.
- Your 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 and lift the cover. You may hear a rattling sound when you unscrew the cover.
2. **Hold the inhaler upright with the red grip downwards** (Fig.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 back again as far as it will go. It does not matter which way you turn first. During this procedure you will hear a click. It does not matter whether the click comes on the first or the second twist. Your inhaler is now loaded and ready for use. Only load your Turbuhaler when you need to use it.
4. Hold your Turbuhaler away from your mouth. Breathe out gently (as far as is comfortable). Do not breathe out through the mouthpiece.
5. Place the mouthpiece gently between your teeth, close your lips. Breathe in as hard as you can through your mouth. (Fig. 3). Do not chew or bite on the mouthpiece.



Figure 2



6. **Remove the inhaler from your mouth. Then breathe out gently.**

The amount of medicine that is inhaled is very small. This means you may not be able to taste it after inhalation. If you have followed the instructions, you can still be confident that you have inhaled the dose and the medicine is now in your lungs.

Figure 3



7. If more than one inhalation has been prescribed, repeat steps 2-6.
8. After use, replace the cover by screwing it back on tightly.
9. After your daily morning and/or evening doses, rinse your mouth with water and spit it out.

Do not try to remove or twist the mouthpiece. It is fixed to your inhaler and must not be taken off. Do not use your Turbuhaler if it has been damaged or if the mouthpiece has come apart from it.

As with all inhalers, caregivers should ensure that children use correct inhalation technique, as described above.

### **Cleaning your inhaler**

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

### **When to start using a new inhaler**

- The dose indicator (figure 4) tells you how many doses (inhalations) are left in your inhaler, starting with either 60 or 120 doses when it is full.
- The dose indicator is marked in intervals of 10 doses. Therefore, it does not show every dose.
- 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' on the red background has reached the middle of the window (figure 5), you must start using your new Symbicort Turbuhaler.

#### **Note:**

- The grip will still twist and 'click' even when your inhaler is empty.
- The sound that you hear as you shake your inhaler is produced by a drying agent and not the medicine. Therefore, the sound does not tell you how much medicine is left in your inhaler.
- If you load your Symbicort 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.

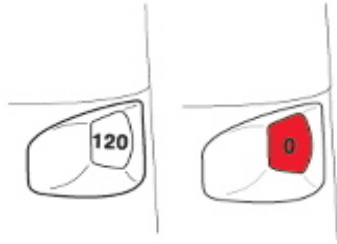


Figure 4

Figure 5

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

You might experience any of the following symptoms: tremor, headache or rapid heartbeat.

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 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), 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 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. Refer to 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:**

**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.

**Uncommon side effects, may affect up to 1 in 100 patients:**

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea.
- Fast heart beat.
- Bruising of the skin.
- Muscle cramps.
- Blurred vision.

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

- Rash, itching

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

**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.

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) - 810 mcg/dose.

### **What does the medicine look like and what are the contents of the package:**

Symbicort Turbuhaler 80/4.5 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 76 30316 00

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