

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

The medicine is dispensed with a doctor's prescription only

BUDICORT®

100 mcg

TURBUHALER®

Powder for Inhalation

BUDICORT®

200 mcg

TURBUHALER®

Powder for Inhalation

Composition:

Each dose contains:

Budesonide 100 mcg

Budesonide 200 mcg

For inactive ingredients, please refer to Section 6 - "Further Information".

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.

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?

Treatment of bronchial asthma.

Therapeutic group:

Corticosteroid.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

You are sensitive to Budesonide or to any of the other ingredients contained in the medicine.

Special warnings regarding use of Budicort Turbuhaler:

Before treatment with Budicort Turbuhaler tell your doctor if:

- You have a lung infection.
- You have a cold or chest infection or any problems with breathing.
- You have or have ever had tuberculosis (TB).
- You have liver function problems.

If you experience blurred vision or other visual disturbances contact your doctor.

Drug interactions

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

Especially inform the doctor or pharmacist if you are taking:

- Steroid medicines.
- Medicines to treat fungal infections (such as itraconazole and ketoconazole).
- Medicines to treat HIV (such as ritonavir or cobicistat-containing products).

Pregnancy, breast-feeding and fertility:

- If you are pregnant, breast-feeding, may be pregnant or are planning pregnancy, consult your doctor before using Budicort Turbuhaler. Do not use Budicort Turbuhaler unless your doctor tells you to.
- If you get pregnant during treatment with Budicort Turbuhaler, do not stop using Budicort Turbuhaler but talk to your doctor immediately.

Driving and using machines

Budicort Turbuhaler is not likely to affect you being able to drive or use any tools or machines.

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.

The dosage and manner of treatment will be determined by the doctor only.

If Budicort Turbuhaler is to be used by a child, make sure the use it correctly as the doctor instructions.

Do not exceed the recommended dose.

Duration of treatment-

- It is important to use Budicort Turbuhaler every day, even if you do not have asthma symptoms every day.
- Your breathing may improve within 2 days of treatment. However, it can take up to 4 weeks for the medicine to have its full effect.

Important information about your asthma symptoms

- If you feel you are getting breathless or wheezy while using Budicort Turbuhaler, you should continue treatment but go to see the doctor as soon as possible, as you may need additional treatment.

Contact the doctor immediately if:

- Your breathing is getting worse or you wake up at night with asthma.
- Your chest feels tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your condition is not being properly controlled and you may need different or additional treatment immediately.

Use your Budicort Turbuhaler every day. Daily use helps to prevent asthma symptoms from happening. Your doctor will advise you of the correct and lowest dose to control your asthma.

If you have been taking steroid tablets for treatment of your asthma, your doctor may instruct you to reduce the number of tablets that you take once you start to use Budicort Turbuhaler.

Your doctor may consider adding steroid tablets to your treatment plan during periods of stress or a severe asthma attack before surgery of any sort.

How to prepare a new inhaler for first use

Before using Budicort Turbuhaler for the first time you need to prepare it for use.



Unscrew the white protective cover and lift it off.



Hold the inhaler upright with brown grip at the bottom. Do not hold the mouthpiece when you turn the grip. Load the inhaler with one dose by turning the brown grip in one direction until it stops and then back to the original position until it stops. It does not matter which way you turn first. You should hear a click sound. Perform the procedure twice.

The Turbuhaler is now ready for use, and you should not repeat the above procedure again. To take a dose from the inhaler, please follow the instructions below.

How to take an inhalation

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

1. Unscrew the white protective cover and lift it off.
2. **Hold your inhaler upright** with the brown grip at the bottom.
3. **Do not hold the mouthpiece** when you load your Turbuhaler. To load your Turbuhaler with a dose, turn the brown grip in one direction until it stops. Then turn it back to the original position until it stops. You should hear a click sound. Your Turbuhaler is now loaded and ready to use. Only load your Turbuhaler when you need to use it. (It does not matter which way you turn it first).
4. Hold your Turbuhaler away from your mouth. **Breathe out** gently (as far as is comfortable). **Do not breathe out** through the inhaler.



5. Place the mouthpiece gently between your teeth. Close your lips. **Breathe in as deeply and as hard** as you can through your mouth. Do not chew or bite on the mouthpiece.

6. **Remove your inhaler from your mouth. After removal of the inhaler breathe out gently.** The amount of powder in Budicort Turbuhaler dose 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.

7. **If you need an additional dose, repeat steps 2 to 6.**

8. **Replace the protective cover by screwing it back on tightly after use.**



9. **Rinse your mouth out with water after inhaling your prescribed dose.**

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

Cleaning the Turbuhaler

Wipe the outside of the mouthpiece once a week with a dry tissue. Do not use water or other liquids to clean the mouthpiece.

When to start using a new Turbuhaler

When you first see a red mark in the indicator window, there are about 20 doses left in the inhaler.

You will then need to see your doctor for another prescription.

When the red mark has reached the bottom of the indicator window, you must start using the new inhaler.



Note:

- The brown grip will still twist and 'click' even when your Turbuhaler is empty.
- The sound that you hear as you shake your Turbuhaler is produced by a drying agent and not the medicine. Therefore the sound does not tell you how much medicine is left in the Turbuhaler.
- If you load the Turbuhaler more than once by mistake before taking your dose, you will still only receive one dose.

If you have accidentally taken a higher dosage

It is important to take the dosage as stated on the pharmacy label on the pack or according to doctor's instructions. You should not increase or decrease your dose without talking with the doctor. If you have taken an overdose, or if a child has accidentally swallowed the medicine, immediately contact a doctor or go to a hospital emergency room, and bring the package of the medicine with you.

If you have forgotten to take the medicine - skip the missed dose and take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Budicort Turbuhaler

Even if the condition of your asthma improves, do not stop treatment with the medicine without instructions from the doctor.

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 Budicort 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 Budicort Turbuhaler and refer to the doctor immediately if any of the following side effects appears:

- Swelling of the face, particularly around the mouth (with possible swelling of the lips, tongue, eyes and ears), rash, itching, contact dermatitis (a skin problem), hives, bronchospasm (tightening of the muscles in the airways which causes wheezing). This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 patients.
- Sudden wheezing after inhaling the medicine. If this happens, also use your 'reliever' inhaler straight away. This happens very rarely, affecting less than 1 in 10,000 patients.

Other possible side effects:

Common side effects (may affect up to 1 in 10 patients):

- Thrush (a fungal infection) in the mouth - This is less likely if you rinse your mouth out with water after using Budicort Turbuhaler.
- Mild sore throat, coughing and a hoarse voice.
- Pneumonia (infection of the lung) in COPD patients.

Refer to the doctor if you have one or more of the following symptoms while taking Budicort Turbuhaler, they could be symptoms of a lung infection:

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

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

- Feeling worried, restless and nervous.
- Depression.
- Trembling.
- Cataract (clouding of the lens in the eye).

- Muscle cramps.
- Blurred vision.

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

- Sleeping problems, feeling over-excited or irritable. These effects are more likely to occur in children.
- Bruising of the skin.
- Loss of voice.
- Hoarse voice (in children).

Inhaled corticosteroids may affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time, for example 400 micrograms or more daily for several years. The effects include:

- changes in bone density.
- glaucoma (increased pressure in the eye)
- a slowing of the rate of growth of children and adolescents (rare). If high doses are given over several years, final adult height may be reduced by about 1 cm.
- an effect on the adrenal gland (a small gland next to the kidney) (rare).

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

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) 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.

Storage conditions:

- Do not store at a temperature above 30°C.
- When not in use, your Turbuhaler should be stored with the protective cover tightened.

6. FURTHER INFORMATION

The preparation contains the active ingredient Budesonide. The preparation has 2 dosages:

Budicort Turbuhaler 100 contains 200 doses (inhalations). Each metered dose contains 100 micrograms of budesonide.

Budicort Turbuhaler 200 contains 100 doses (inhalations). Each metered dose contains 200 micrograms of budesonide.

What does the medicine look like and what are the contents of the package - Budicort Turbuhaler is an inhaler containing your medicine. Each inhaler contains 100 or 200 doses (inhalations), the inhaler is white with a brown grip.

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

Budicort Turbuhaler 100 mcg: 057 98 26940 00

Budicort Turbuhaler 200 mcg: 057 97 26942 00

Manufacturer:

AstraZeneca AB, Sweden

License holder and importer:

AstraZeneca (Israel) Ltd.,

P.O. Box 1455, Hod Hasharon 4524075

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