

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

The medicine is dispensed with a doctor's prescription only

BUDICORT® RESPULES 0.5 mg/2 ml

BUDICORT® RESPULES 1 mg/2 ml

Suspension for Inhalation

COMPOSITION

Budicort® Respules 0.5 mg/2 ml contains: Budesonide 0.5 mg

Budicort® Respules 1 mg/2 ml contains: Budesonide 1.0 mg

For inactive ingredients, please see Section 6 – Further Information.

Read the package insert 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 THE MEDICINE INTENDED FOR?

For treatment of bronchial asthma.

Therapeutic group

Corticosteroids

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

you are sensitive or have had sensitivity to budesonide or to any of the medicine's ingredients (see section 6).

! Special warnings regarding use of Budicort Respules

Before treatment with Budicort Respules, tell the doctor if:

- you suffer from a lung infection
- you have a cold, are suffering from a chest infection
- you suffer from liver problems

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

Drug interactions

If you are taking, or have 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:

- steroidal medicines
- medicines for treatment of fungal infections (such as medicines that contain ketoconazole or itraconazole)
- medicines for treatment of HIV (such as medicines that contain cobicistat or ritonavir)

Pregnancy, breast-feeding and fertility

If you are pregnant, breastfeeding, may be pregnant or planning to become pregnant, consult your doctor or pharmacist before using Budicort Respules.

Do not use Budicort Respules without the doctor's instruction.

If you get pregnant while using Budicort Respules, do not stop the treatment with Budicort Respules, but talk to the doctor immediately.

Driving and using machines

Budicort Respules is not likely to affect your ability to drive or use 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 not sure about the dosage or manner of treatment.

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

The doctor will prescribe the dosage suitable for you in accordance with the severity of the disease.

Do not exceed the recommended dose.

- Budicort Suspension for Inhalation is administered by using an inhalation device. When breathing in through the mouthpiece or face mask the medicine penetrates into the airways. See instruction for use below.
Do not use an ultrasonic nebuliser with Budicort Respules.
- Your asthma may improve within 2 days. However, it can take up to 4 weeks for the medicine to have full effect. It is important to use Budicort Respules every day, even if you have no asthma symptoms at the time.

Manner of use

Attention!

Do not swallow!

Shake before use!

The dosage will be determined by the doctor. The dosage depends on the severity of the disease. The doctor may lower your dose if your asthma improves.

INSTRUCTIONS FOR USE OF BUDICORT® RESPULES

(Read carefully before use)

1. Detach one respule from the strip. Leave the rest in the foil envelope.
2. Mix the suspension before use by gently shaking the dosage unit
3. Hold the respule upright, twist the top part of the respule until it detaches.
4. Place the open end of the Respule inside the nebuliser cup. Squeeze slowly the contents of the open Respule into the reservoir of the nebuliser.
5. Throw the empty Respule away. Put the top back on the nebuliser cup.

6. Connect one end of the cup to the face mask or mouthpiece.
7. Connect the other end of the cup to the air pump.
8. Gently shake the cup.
9. Turn on the nebuliser and breathe in the mist calmly and deeply using the face mask or mouthpiece. If you are using face mask. Make sure the face mask fits tightly.
10. The treatment is complete when the fine mist will stop coming out of the mask or mouthpiece.
11. How long it takes to nebuliser all the medicine depends on the type of equipment you use and on the amount of medicine you use.
12. Rinse your mouth with water. Spit out the water. Do not swallow it. If you have used a face mask, wash your face as well.
13. After each use, you must wash the nebuliser cup and mouthpiece/face mask in warm soapy water and rinse well. After washing, dry these parts by connecting to the air outlet of the inhalation device and blow air through them.

Important information regarding the symptoms of your asthma:

If you experience difficulty breathing or wheezing while you are using Budicort Respules, continue treatment, but refer to the doctor as soon as possible, because you may need additional treatment.

Refer to the doctor immediately if the following effects occur:

- your breathing becomes worse, you wake up during the night with asthma,
- tightness in your chest in the morning or the chest tightness continues longer than usual

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

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you have forgotten to take the medicine –Skip the forgotten dose and take the next dose as usual.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, use of Budicort Respules may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Side effects requiring special attention:

Stop using Budicort Respules and refer to the doctor immediately if any of the following occur:

- Swelling of the face, particularly around the mouth (with possible swelling of the lips, tongue, eyes, 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 effect is rare, can happen in less than 1 in 1,000 patients.
- Sudden wheezing after inhaling your medicine. This happens very rarely, less than 1 in every 10,000 patients.

Other side effects:

Common side effects (effects that occur in up to 1 in 10 patients):

- Oral thrush; you can reduce the frequency of this effect by making sure

to rinse your mouth out with water after using the medicine.

- Mild sore throat, cough and hoarseness.
- Pneumonia in COPD patients.

Refer to the doctor if you suffer from one or more of the following symptoms while taking Budicort Respules, these symptoms may be sign for pneumonia:

- 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
- Shaking
- Cataract (clouding of the lens in the eye)
- Muscle cramps
- Blurred vision

Rare side effects (may affect less than 1 in 1,000 patients):

- A rash on your face after using the mask. The frequency of this effect can be reduced by making sure to wash your face after using the mask.
- Sleeping disturbances, feeling over-excited or irritable. These side effects usually occur more frequently in children.
- Bruising of the skin
- Loss of voice
- Hoarseness (in children)

Inhaled corticosteroids may affect the normal production of steroid hormones in your body, particularly after taking a high dosage for a long time. The affect may include:

- Changes in bone density
- Glaucoma (increased intraocular pressure)

- Slowing of growth in children and adolescents (rare). If high doses are given over several years, final height may be reduced by about 1 cm.
- An effect on the adrenal gland (a small gland next to the kidney) (rare)

These side effects are less likely to occur with inhaled corticosteroids in comparison with use of oral steroids.

If you experience any of these effects, or if you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

If one of the side effects worsens, or if you suffer from side effects not mentioned in this leaflet, consult the doctor.

Reporting side effect

Side effects can be reported to the Ministry of Health by using the online form for reporting side effects, found on the Ministry of Health homepage

www.health.gov.il

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 should 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 a doctor!
 - Do not use the medicine after the expiry date (exp. date) that appears on the package/envelope/respule. The expiry date refers to the last day of the indicated month.
 - Keep this medicine in a cold and dark place below 30°C. Do not refrigerate.
 - Store the packs of respules in the original package in the envelope, vertically, and protect from light.

- After opening the envelope, use the remaining respules within 3 months.
Note: it is best to mark the opening date on the foil envelope to help you remember. A respule that has been opened must be used within 12 hours only, and then the remaining medicine must be discarded.
- Do not store different medicines in the same package.

6. FURTHER INFORMATION

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

Sodium chloride, sodium citrate, citric acid anhydrous, polysorbate 80, disodium edetate, water for injection.

What the medicine looks like and the content of the package:

Each respule (plastic ampoule) contains 2 ml of a white/cream colored sterile suspension. Every 5 respules are attached in a strip and packed in an aluminium envelope. Each package contains 20 respules (4 envelopes of 5 respules).

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

Budicort Respules 0.5 mg/2 ml: 113132957500

Budicort Respules 1.0 mg/2 ml: 113142957600

Manufacturer:

AstraZeneca AB, Sweden

License Holder:

AstraZeneca (Israel) Ltd.,

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