

INSTRUCTION MANUAL

LASECON 160 mcg/dose Inhalation Aerosol Containing Solution

It is used by breathing through the mouth.

In this Instructions for Use:

1. What is LASECON and what is it used for?
2. Things to consider before using LASECON
3. How to use LASECON?
4. What are the possible side effects?
5. Storing LASECON

Headings are included.

1. What is LASECON and what is it used for?

☐ LASECON contains ciclesonide as an active ingredient. It contains 60 doses in a pressure pack made of aluminum containing 160 micrograms of ciclesonide. LASECON contains ethanol and propellant as excipients.

☐ LASECON is a clear and colorless inhalation solution that is inhaled through the mouth, into the lungs where it will act. It is a preventive medicine that should be used every day. (corticosteroid). It is designed to show its effect only in the lungs after inhalation.

☐ This drug is prescribed to relieve inflammation in all stages of asthma, to expand the airway, to control symptoms and to reduce the need for oral steroids (medicines used in exacerbation of respiratory diseases). It is not recommended for use alone in COPD (Chronic obstructive pulmonary disease).

☐ LASECON allows you to breathe more easily by reducing asthma symptoms such as shortness of breath and the possibility of having an asthma attack. The protective effect of LASECON develops over time. For this reason, you should continue to use the medicine every day, even if you feel well. Before you start using this medicine, carefully read this INSTRUCTIONS FOR USE, because it contains important information for you.

☐ Keep this user manual. You can need to read again.

☐ If you have any further questions, please consult your doctor or pharmacist.

☐ This medicine has been prescribed for you personally, do not give it to others.

☐ During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital.

☐ Follow exactly what is written in this instruction. Do not use high or low doses other than the dose recommended to you about the drug.

2. Things to consider before using LASECON

DO NOT USE LASECON in the following situations

If;

☐ If you are allergic to any of the ingredients (see the list of excipients),

☐ If you are being treated for or have ever had a fungal (fungal), viral, bacterial infection or pulmonary tuberculosis (TB) affecting your lung system;

USE LASECON CAREFULLY in the following situations

If;

☐ If your symptoms are getting worse (cough, shortness of breath, difficulty and wheezing, chest tightness),

☐ If you wake up at night because of your symptoms,

☐ If wheezing occurs immediately after the application,

☐ If allergic effects such as allergic rhinitis (inflammation of the nose) or eczema (itchy and red skin) are observed,

☐ If you have severe asthma,

☐ If severe symptoms such as nausea, vomiting, high fever or diarrhea occur,

☐ If you switch from tablets to LASECON, the risk of adrenal insufficiency associated with corticosteroids may persist for some time. Symptoms of adrenal gland failure (eg, dizziness,

weakness, nausea, loss of appetite, moodiness, hair loss, weakness, headache, memory problems, allergies, food cravings and blood sugar diseases) may be seen for a while.

☒ If you have adrenal insufficiency,

☒ If your quick and short-acting (reliever) inhaler is not giving you relief, contact your doctor immediately.

Moreover;

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using LASECON with food and drink

LASECON has no interaction with food or drink.

Pregnancy

Consult your doctor or pharmacist before using this medication.

☒ If you are pregnant, use LASECON only if recommended by your doctor.

☒ LASECON can be used if the potential benefit to the mother outweighs the potential risk to the baby's development. If your doctor has decided to continue using LASECON; The lowest dose that will provide asthma control should be used.

☒ If you have used corticosteroids during your pregnancy, your child's adrenal gland functions will be carefully monitored.

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

☒ Consult your doctor before using LASECON.

☒ It is not known whether inhaled ciclesonide passes into breast milk.

☒ LASECON may only be prescribed when the benefit to the mother outweighs the potential risk to the baby.

Vehicle and machine use

Inhaled ciclesonide has no or negligible effect on the ability to drive and use machines.

Important information about some of the ingredients of LASECON

It does not contain excipients that require warning.

Concomitant use with other drugs

If you are using a drug against fungi or viruses (such as drugs containing ketoconazole, itraconazole, ritonavir or nelfinavir), inform your doctor about this before using LASECON.

If you are currently using or have recently used any prescription or non-prescription medicine, please inform your doctor or pharmacist about this issue.

3. How to use LASECON?

Instructions for proper use and dose/frequency of administration:

Always use LASECON as your doctor has told you. If you are not sure how to use it, you should consult your doctor or pharmacist.

The inhaler contains 60 puffs (doses). According to the daily application dose recommended by your doctor, this medicine contains enough dose for 1 to 2 months.

Your doctor will tell you how much medicine you should take each day, and this amount is only as much as you need.

☒ The recommended daily dose of LASECON for asthma control in most patients is 160 micrograms.

☒ The daily dose may be reduced in some patients to 80 micrograms, which may be appropriate for asthma control.

☒ The dose of LASECON may need to be increased in patients with severe asthma symptoms.

It can be increased up to 640 micrograms/day, given 320 micrograms twice daily.

However, there is no data confirming the use of high doses for more than 3 months.

If necessary; Your doctor may prescribe corticosteroid tablets and/or antibiotics in case of inflammation.

- Your doctor will adjust the lowest dose necessary to control your asthma.

- You should notice an improvement in your symptoms (cough, shortness of breath, wheezing, chest tightness) within 24 hours.

Application route and method:

In many cases, your doctor will want you to use LASECON once a day, morning or evening. You must carefully follow the instructions your doctor will give you. It is important to use LASECON regularly every day, even if you feel well.

If you need to use your quick and short-acting (reliever) inhaler more than 2 or 3 times a week, you should tell your doctor so that he can review your medicine.

It is important that a doctor, nurse or pharmacist show you how to use LASECON correctly. When used properly, the right amount of medicine reaches the lungs.

The information in this instruction is to remind you of what has been told to you.

You can try a few times in front of the mirror until you are sure that you are using LASECON correctly.

Make sure that no medicine escapes from the top of the inhaler or the side of your mouth while using the medicine.

If you are using the inhaler for the first time or if you have not used the inhaler for more than a week, you should prepare the inhaler before using it. Remove the cap covering the mouthpiece of the inhaler and spray the medicine into the air by pressing the metal cup inside the inhaler 3 times.

Different age groups:

Use in children:

Ciclesonide is not recommended for the treatment of children under 6 years of age because there is no information about its side effects. LASECON should not be used in children under 12 years of age.

Use in the elderly:

Elderly patients do not require dose adjustment.

Special use cases:

Kidney/Liver failure:

No dose adjustment is required in patients with hepatic and/or renal impairment.

Unless your doctor recommends otherwise follow these instructions.

Do not forget to take your medicine on time.

Your doctor will advise you how long your treatment with LASECON will last.

Do not use any other medicine (including over-the-counter medicines) without talking to your doctor.

If you have the impression that the effect of LASECON is too strong or too weak, talk to your doctor or pharmacist.

If you use more LASECON than you should:

No special treatment is required in overdose of LASECON. If you have used more LASECON than you should for a long time, there may be a certain level of adrenal suppression and your adrenal gland functions may need to be controlled.

If you have used more than you should use from LASECON, talk to a doctor or pharmacist.

If you forget to use LASECON

If you forget to use LASECON, skip that dose and continue with the next dose when the time comes.

DO NOT spray twice to make up for the missing dose.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with LASECON is terminated

LASECON works best when taken regularly every day. Use the inhaler until your doctor tells you not to, even if you feel well.

4. What are the possible side effects?

Like all medicines, there may be side effects in people who are sensitive to the substances contained in LASECON.

Side effects are listed as shown in the following categories.

Very common: may occur in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: less than 1 in 10,000 patients

Frequency not known: It can be seen in too few patients to be determined with the available data.

Side effects seen with the use of LASECON are generally mild. In many cases, treatment was continued.

Unusual

- Hoarseness/ hoarseness, increased cough and wheezing after inhalation
- Unpleasant taste, burning in the mouth or throat, inflammation, irritation, dryness
- Nausea, vomiting
- Oral aphthae (oral fungal infections)
- Headache
- Rash and/or eczema causing itching and redness of the skin

Rare

- Immediate or subsequent hypersensitivity (hypersensitivity) reactions such as swelling of the lips, tongue and throat (angioedema). When these symptoms occur, stop taking the drug and seek medical help immediately.
- High blood pressure, palpitations
- Abdominal pain and indigestion

Unknown

- Sleep problems, depression, or feeling anxious, restless, irritable, overexcited or nervous.

LASECON may affect the normal production of steroids in your body. This condition is usually observed in patients receiving long-term and high-dose treatment. These effects:

- Deceleration in the growth of adolescents
- thinning of bones
- Deteriorated vision by causing possible clouding of the eye lens (cataract)
- Vision loss due to abnormally high blood pressure in the eye (glaucoma)
- Monthly face, weight gain in the upper body, thinning of the arms and legs (Cushingoid features, Cushing's syndrome)

The height of adolescent patients who are treated for a long time should be measured regularly.

If the growth rate has slowed, your doctor will adjust your treatment to the lowest effective dose that can control your asthma.

Steroid tablets may cause more side effects than an inhaler like LASECON. If you have taken steroid tablets while using LASECON or before, the risk of side effects related to the tablets may continue for a while.

Having a regular checkup under the supervision of your doctor will ensure that you are getting the right dose of LASECON for you. Regular check-ups also make possible side effects to be noticed in a short time and prevent the possibility of worsening.

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storing LASECON

Keep LASECON out of the sight and reach of children and in its package.

Store at room temperature below 25°C.

Close the mouthpiece cover after each use.

Use in accordance with expiration dates.

Do not use LASECON after the expiry date on the package.

Do not throw away expired or unused medicines! Environment and Urbanism

Give it to the collection system determined by the Ministry.

License owner:

Deva Holding A.S.

Kucukcekmece/ISTANBUL

Tel: 0212 692 92 92

Fax: 0212 697 00 24

E-mail: deva@devaholding.com.tr

Production place:
Deva Holding A.S.
Kapaklı/TEKIRDAG