

Patient Information

ORTIKOS (or-TEE-kos)

(budesonide)

extended-release capsules, for oral use

Read this Patient Information before you start taking ORTIKOS and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is ORTIKOS?

ORTIKOS is a prescription corticosteroid medicine used to treat mild to moderate Crohn's disease that affects part of the small intestine (ileum) and part of the large intestine (ascending colon):

- in people 8 years of age and older with active Crohn's disease
- in adults to help keep symptoms from coming back for up to 3 months

It is not known if ORTIKOS is safe and effective in children under 8 years of age, or in children 8 to 17 years of age who weigh 55 pounds (25 kg) or less, for the treatment of mild to moderate active Crohn's disease that affects part of the small intestine and part of the large intestine.

It is not known if ORTIKOS is safe and effective in children to help keep symptoms of mild to moderate Crohn's disease that affects part of the small intestine and part of the large intestine from coming back.

Do not take ORTIKOS if:

- you are allergic to budesonide or any of the ingredients in ORTIKOS. See the end of this leaflet for a complete list of ingredients in ORTIKOS.

Before you take ORTIKOS tell your healthcare provider if you have any other medical conditions including if you:

- have liver problems.
- are planning to have surgery.
- have chicken pox or measles or have recently been near anyone with chicken pox or measles.
- have an infection.
- have diabetes or glaucoma or have a family history of diabetes or glaucoma.
- have cataracts.
- have or had tuberculosis.
- have high blood pressure (hypertension).
- have decreased bone mineral density (osteoporosis).
- have stomach ulcers.
- are pregnant or plan to become pregnant. ORTIKOS may harm your unborn baby. Talk to your healthcare provider about the possible risk to your unborn baby if you take ORTIKOS when you are pregnant. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during your treatment with ORTIKOS.
- are breastfeeding or plan to breastfeed. It is not known if ORTIKOS passes into your breast milk or if it will affect your baby. Talk to your healthcare provider about the best way to feed your baby if you take ORTIKOS.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ORTIKOS and other medicines may affect each other causing side effects.

How should I take ORTIKOS?

- Take ORTIKOS exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how many ORTIKOS to take. Your healthcare provider may change your dose if needed.
- Take ORTIKOS 1 time each day in the morning.
- Take ORTIKOS capsules whole. Do not chew or crush ORTIKOS capsules before swallowing.
- If you take too many ORTIKOS capsules call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking ORTIKOS?

- Do not drink grapefruit juice during your treatment with ORTIKOS. Drinking grapefruit juice can increase the level of ORTIKOS in your blood.

What are the possible side effects of ORTIKOS?

ORTIKOS may cause serious side effects, including:

- **Effects of having too much corticosteroid medicine in your blood (hypercorticism).** Long-time use of ORTIKOS can cause you to have too much corticosteroid medicine in your blood. Tell your healthcare provider if you have any of the following signs and symptoms of hypercorticism:
 - acne
 - thicker or more hair on your body and face
 - bruise easily
 - a fatty pad or hump between your shoulders (buffalo hump)
 - rounding of your face (moon face)
 - pink or purple stretch marks on the skin or your abdomen, thighs, breasts and arms
 - ankle swelling

- **Adrenal suppression.** When ORTIKOS is taken for a long period of time (chronic use), kidney (adrenal) suppression can happen. This is a condition in which the adrenal glands do not make enough steroid hormones. Symptoms of adrenal suppression include: tiredness, weakness, nausea and vomiting and low blood pressure. Tell your healthcare provider if you are under stress or have any symptoms of adrenal suppression during treatment with ORTIKOS.
- **Worsening of allergies.** If you take certain other corticosteroid medicines to treat allergies, switching to ORTIKOS may cause your allergies to come back. These allergies may include a skin condition called eczema or inflammation inside your nose (rhinitis). Tell your healthcare provider if any of your allergies become worse while taking ORTIKOS.
- **Increased risk of infection.** ORTIKOS weaken your immune system. Taking medicines that weaken your immune system makes you more likely to get infections. Avoid contact with people who have contagious diseases, such as chicken pox or measles, while taking ORTIKOS. Tell your healthcare provider right away if you come in contact with anyone who has chicken pox or measles.
- Tell your healthcare provider about any signs or symptoms of infection during treatment with ORTIKOS, including:
 - fever
 - chills
 - pain
 - feeling tired
 - aches
 - nausea and vomiting

The most common side effects of ORTIKOS in adults include:

- headache
- infection in your air passages (respiratory infection)
- nausea
- back pain
- indigestion
- dizziness
- stomach area (abdominal) pain
- gas
- vomiting
- tiredness
- pain

The most common side effects of ORTIKOS in children 8 to 17 years of age, who weigh more than 55 pounds (25 kg), are similar to the most common side effects in adults.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ORTIKOS. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ORTIKOS?

- Store ORTIKOS at room temperature between 68° to 77°F (20° to 25°C).
- Keep ORTIKOS in a tightly closed container.

Keep ORTIKOS and all medicines out of reach of children.

General information about the safe and effective use of ORTIKOS.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ORTIKOS for a condition for which it was not prescribed. Do not give ORTIKOS to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about ORTIKOS that is written for health professionals.

What are the ingredients in ORTIKOS?

Active ingredient: budesonide

Inactive ingredients: acetyl tributyl citrate, corn starch, ethylcellulose aqueous dispersion, methacrylic acid and ethyl acrylate copolymer dispersion, polysorbate 80, simethicone emulsion, sucrose, talc, and triethyl citrate.

Capsule shell contains gelatin, iron oxide black (for 6 mg), iron oxide red, iron oxide yellow, sodium lauryl sulphate and titanium dioxide.

The imprinting ink contains, black iron oxide, potassium hydroxide and shellac.

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Manufactured by:
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For more information, call 1-800-818-4555.