

MEDICATION GUIDE
ICOTYDE™ (ai-koh-tide)
(icotrokinra)
tablets, for oral use

What is the most important information I should know about ICOTYDE?

- **Infections.** Medicines that interact with the immune system, such as ICOTYDE, may lower your ability to fight infections and may increase your risk of infections. Your healthcare provider may check you for infections and tuberculosis (TB) before starting treatment and may treat you for TB before you begin treatment with ICOTYDE if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with ICOTYDE. Tell your healthcare provider right away if you have any infection or have symptoms of an infection, including:
 - fever, sweat, or chills
 - cough
 - shortness of breath
 - blood in your mucus (phlegm)
 - muscle aches
 - warm, red, or painful skin or sores on your body different from your psoriasis
 - weight loss
 - diarrhea or stomach pain
 - burning when you urinate or urinating more often than normal

See “**What are the possible side effects of ICOTYDE?**” for more information about side effects.

What is ICOTYDE?

ICOTYDE is a prescription medicine used to treat moderate-to-severe plaque psoriasis in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg), who may benefit from taking injections or medicines by mouth (systemic therapy) or treatment using ultraviolet or UV light (phototherapy).

It is not known if ICOTYDE is safe and effective in children under 12 years of age or who weigh less than 88 pounds (40 kg).

Before taking ICOTYDE, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection that does not go away or that keeps coming back.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). Avoid receiving live vaccines during treatment with ICOTYDE.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if ICOTYDE can harm your unborn baby.
Pregnancy Safety Study. There is a pregnancy safety study for women who take ICOTYDE during pregnancy. The purpose of this study is to collect information about the health of you and your baby. If you are pregnant or become pregnant during treatment with ICOTYDE, you can report your pregnancy by calling 1-800-526-7736 or visiting www.ICOTYDE.com.
- are breastfeeding or plan to breastfeed. It is not known if ICOTYDE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ICOTYDE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take ICOTYDE?

- Take ICOTYDE exactly as your healthcare provider tells you to take it.
- Take ICOTYDE 1 time a day.
- Take ICOTYDE when you wake up on an empty stomach with water.
- Wait at least 30 minutes after taking ICOTYDE before eating food.
- Swallow ICOTYDE tablets whole.
- **Do not** crush, split, or chew ICOTYDE tablets.
- If you cannot swallow ICOTYDE tablets whole:
 - Place 1 ICOTYDE tablet in a cup containing at least 120 mL (4 ounces) of water.
 - Wait a few minutes for the tablet to break up (disperse) in the water. The tablet may not completely disperse. The mixture may look yellow, milky, or cloudy. Small pieces may be seen in the water, which are safe to swallow.
 - Gently swirl the cup before swallowing the mixture.
 - Add at least 120 mL (4 ounces) of additional water to the cup and completely swallow all of the mixture to make sure that you take your full dose of ICOTYDE.
 - Take the ICOTYDE and water mixture within 15 minutes of preparation.
- If you miss a dose of ICOTYDE, take the dose as soon as you remember and go back to your regular schedule the next day.

What are the possible side effects of ICOTYDE?

ICOTYDE may cause serious side effects. See “What is the most important information I should know about ICOTYDE?”

The most common side effects of ICOTYDE include:

- headache
- nausea
- cough
- fungal infection
- tiredness

These are not all the possible side effects of ICOTYDE.

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 ICOTYDE?

- Store ICOTYDE at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ICOTYDE in the original bottle to protect from moisture.
- The ICOTYDE bottle comes with a child-resistant cap and contains a desiccant packet to keep your medicine dry (protect it from moisture). Do not throw away (discard) the desiccant packet.

Keep ICOTYDE and all medicines out of the reach of children.

General information about the safe and effective use of ICOTYDE.

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

What are the ingredients of ICOTYDE?

Active ingredient: icotrokinra

Inactive ingredients: colloidal silicon dioxide, crospovidone, magnesium stearate, and silicified microcrystalline cellulose. The film coating contains glyceryl monocaprylocaprate, iron oxide yellow, macrogol polyvinyl alcohol graft polymer, polyvinyl alcohol partially hydrolyzed, talc, and titanium dioxide.

Manufactured for: Janssen Biotech, Inc., Horsham, PA 19044, USA

For patent information: www.janssenpatents.com

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For more information, go to www.ICOTYDE.com or call 1-800-526-7736.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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