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2. Eflomithine

Eflornithine

Generic name: eflornithine [ef-LOR-ni-theen]

Brand name: Iwilfin

Dosage form: oral tablet (192 mg)

Drug class: Miscellaneous antineoplastics



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Uses Side effects Warnings Before taking Dosage Interactions

What is effornithine?

Eflornithine is used in adults and children to keep high-risk neuroblastoma (HRNB), a certain type of cancer, from coming back.

Eflornithine is given after prior treatments partially worked.

Eflornithine may also be used for purposes not listed in this medication guide.

Eflornithine side effects

Get emergency medical help if you have **signs of an allergic reaction**: hives, difficult breathing, swelling of your face, lips, tongue, or throat.

Eflornithine may cause serious side effects. Call your doctor at once if you have:

- hearing problems such as ringing in your ears or hearing loss;
- liver problems--loss of appetite, nausea, vomiting, stomach pain (upper right side), tiredness, itching, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes); or
- low blood cell counts--fever, chills, tiredness, mouth sores, skin sores, easy bruising, unusual bleeding, pale skin, cold hands and feet, feeling light-headed or short of breath.

Your cancer treatments may change, be delayed, or permanently discontinued if you have certain side effects.

Common side effects of effornithine may include:

- fever, diarrhea, vomiting;
- ear, sinus, or skin infections;
- pneumonia;

- urinary infection (UTI);
- cold or allergy symptoms such as cough, stuffy, runny, or itchy nose, sneezing, sore throat; or
- red or swollen eyes (pinkeye).

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

i Eflornithine side effects (more detail)

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Warnings

Use only as directed. Tell your doctor if you use other medicines or have other medical conditions or allergies.

Before taking this medicine

Tell your doctor if you have ever had:

- · hearing problems; or
- · low blood cell counts.

Eflornithine can harm an unborn baby if the mother or the father is using eflornithine.

• If you are a woman, you may need a pregnancy test to make sure you are not pregnant. Use birth control while

using this medicine and for at least 1 week after your last dose.

• If you are a man, use birth control if your sex partner is able to get pregnant. Keep using birth control for at least 1 week after your last dose.

• Tell your doctor right away if a pregnancy occurs.

Do not breastfeed while using this medicine, and for at least 1 week after your last dose.

How should I take effornithine?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose. Use the medicine exactly as directed.

Your doctor will perform tests to make sure effornithine is the right treatment for you.

Eflornithine is usually taken twice per day, with or without food. Your doctor will determine the right treatment schedule for you.

Swallow the tablet whole. If you cannot swallow a tablet whole, effornithine can be chewed, or crushed then mixed with soft food or liquid.

Read and carefully follow the instructions provided to you on how to prepare and take effornithine if you are unable to swallow the medicine. Ask your doctor or pharmacist if you don't understand these instructions.

Doses are based on body surface area (height and weight). Your dose may change if you gain or lose weight or if you are still growing.

You will need frequent medical tests before starting and during treatment, including hearing tests. Your next dose may change or be delayed based on the results.

If you vomit shortly after taking eflornithine, do not take another dose. Take your next dose as scheduled.

Store at room temperature away from moisture and heat.

Effornithine dosing information

Usual Adult Dose for Neuroblastoma:

Body Surface Area (BSA)

BSA greater than 1.5 m2: 768 mg (four tablets) orally twice a day

BSA 0.75 to 1.5 m2: 576 mg (three tablets) orally twice a day

BSA 0.5 to less than 0.75 m2: 384 mg (two tablets) orally twice a day BSA 0.25 to less than 0.5 m2: 192 mg (one tablet) orally twice a day

Duration: For 2 years or until recurrence of disease or unacceptable toxicity.

Comments:

-Before initiating this drug, a complete blood count, liver function tests, and baseline audiogram tests should be performed.

-Recalculate BSA dosage every 3 months during treatment.

Use: To reduce the risk of relapse in patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy, including anti-GD2 immunotherapy

Usual Pediatric Dose for Neuroblastoma:

Body Surface Area (BSA)

BSA greater than 1.5 m2: 768 mg (four tablets) orally twice a day

BSA 0.75 to 1.5 m2: 576 mg (three tablets) orally twice a day

BSA 0.5 to less than 0.75 m2: 384 mg (two tablets) orally twice a day

BSA 0.25 to less than 0.5 m2: 192 mg (one tablet) orally twice a day

Duration: For 2 years or until recurrence of disease or unacceptable toxicity.

Comments:

- -Before initiating this drug, a complete blood count, liver function tests, and baseline audiogram tests should be performed.
- -Recalculate BSA dosage every 3 months during treatment.

Use: To reduce the risk of relapse in patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy, including anti-GD2 immunotherapy

Detailed Eflornithine dosage information

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if your next dose is due within 7 hours. **Do not** use two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking effornithine?

Follow your doctor's instructions about any restrictions on food, beverages, or activity.

What other drugs will affect effornithine?

Other drugs may affect effornithine, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all other medicines you use.

<u>Effornithine drug interactions</u> (more detail)

Does eflornithine interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

+

Enter a drug name Add

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Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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Availability Rx Prescription only Pregnancy & Lactation Risk data available CSA Schedule* N/A Not a controlled drug Approval History Drug history at FDA

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