

PATIENT INFORMATION

IWILFIN™ (I-WILL-fin) (eflornithine) tablets

What is IWILFIN?

IWILFIN is a prescription medicine used to reduce the risk of relapse in adults and children with high-risk neuroblastoma (HRNB) who have had at least a partial response to certain prior therapies.

Before you take IWILFIN, tell your healthcare provider about all of your medical conditions, including if you:

- have hearing problems
- are pregnant or plan to become pregnant. IWILFIN can harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with IWILFIN or think you may be pregnant.
 - **Females** who are able to become pregnant should have a pregnancy test before starting treatment with IWILFIN. You should use effective birth control during treatment with IWILFIN and for 1 week after the last dose.
 - **Males** who have female partners who are able to become pregnant should use effective birth control during treatment with IWILFIN and for 1 week after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if IWILFIN passes into your breast milk. Do not breastfeed during treatment with IWILFIN and for 1 week after the last dose.

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 IWILFIN?

- Take IWILFIN exactly as your healthcare provider tells you to take it.
- Take IWILFIN 2 times a day with or without food.
- Swallow tablets whole. If you cannot swallow tablets whole, IWILFIN can be chewed, or crushed then mixed with soft food or liquid. If you are crushing IWILFIN tablets:
 - IWILFIN can be crushed then mixed with 2 tablespoons of soft food or liquid.
 - Eat the entire mixture.
 - If any crushed tablet pieces remain, mix with another small amount (about 2 tablespoons) of soft food or liquid.
 - Take all of the mixture within 1 hour of mixing. Throw away any mixture left after 1 hour.
- If you miss a dose of IWILFIN, take it as soon as you remember. If it is within 7 hours of your next scheduled dose, skip the missed dose and take your next dose at your regular time.
- If you vomit after taking a dose, do not take an extra dose. Take your next dose at your regular time.

What are the possible side effects of IWILFIN?

IWILFIN may cause serious side effects, including:

- **Low blood cell counts.** IWILFIN can cause low blood cell counts and failure of your bone marrow to make enough platelets, red blood cells, or white blood cells. Your healthcare provider will monitor your blood cell counts before starting and during treatment with IWILFIN. Tell your healthcare provider right away if you develop symptoms of low blood cell counts, including:
 - fever (temperature 100.4°F or higher)
 - feeling unusually tired or weak
 - easy bruising or bleeding
 - shortness of breath
 - blood in your urine or stools
 - chills or shivering
- **Liver problems.** Your healthcare provider will do blood tests before starting, every month for the first 6 months, and regularly during treatment with IWILFIN to check your liver. Tell your healthcare provider if you develop symptoms of liver problems, including:
 - your skin or the white part of your eyes turns yellow (jaundice)
 - nausea or vomiting
 - dark or “tea-colored” urine
 - easy bruising or bleeding
 - light-colored stools (bowel movements)
 - loss of appetite
 - pain, aching, or tenderness on the right side of your stomach-area (abdomen)
- **New or worsening hearing loss.** Hearing loss is common during treatment with IWILFIN and can also be serious. Your healthcare provider will check your hearing before you start and during treatment with IWILFIN. Some people have needed to use hearing aids. Tell your healthcare provider right way if you get ringing in your ears or any new or worsening hearing loss.

The most common side effects of IWILFIN include:

- ear infection
- diarrhea
- cough
- sinus infection
- pneumonia
- upper respiratory tract infection
- red and swollen eyes (pink eye)
- vomiting
- stuffy, runny, itchy nose or sneezing (allergic rhinitis)
- fever
- skin infection
- urinary tract infection

These are not all the possible side effects of IWILFIN.

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 IWILFIN?

- Store IWILFIN at room temperature between 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of IWILFIN:

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

What are the ingredients in IWILFIN?

Active ingredient: eflornithine

Inactive ingredients: silicified microcrystalline cellulose, partially pregelatinized maize starch, colloidal silicon dioxide, and vegetable source magnesium stearate.

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For more information, go to www.IWILFIN.com or call 1-877-IWILFIN.