

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Iwilfin

Tablets

Active ingredient

Each tablet contains eflornithine (as hydrochloride monohydrate) 192 mg

Inactive ingredients and allergens in this medicine: see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Iwilfin is used to reduce the risk of disease relapse in adults and children with high-risk neuroblastoma (a type of cancer formed in neural cells called neuroblasts (immature neural tissue)) who have demonstrated at least a partial response to certain prior therapies.

Therapeutic group: ornithine decarboxylase inhibitor.

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
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Special warnings about using this medicine

Before treatment with Iwilfin, tell your doctor if:

- You have hearing problems

Additional warnings

- Use of Iwilfin increases the risk of myelosuppression (bone marrow suppression) (see section 4 'Side effects').
- Use of Iwilfin increases the risk of hepatotoxicity (liver injury) (see section 4 'Side effects').
- Use of Iwilfin increases the risk of hearing loss (see section 4 'Side effects').

Tests and follow-up

Before you start using the medicine and throughout the treatment period, your doctor will refer you for the following tests: blood count, liver function (before starting treatment, every month for the first 6 months of treatment, and then every 3 months or as clinically indicated), and hearing test (before starting treatment and then every 6 months or as clinically indicated).

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Using this medicine and food

Can be taken with or without food.

Pregnancy and breastfeeding

Pregnancy

Do not use the medicine without consulting your doctor if you are pregnant or plan to become pregnant. Iwilfin can harm your fetus and cause pregnancy loss. Tell your doctor immediately if you become pregnant or think that you may be pregnant during treatment with Iwilfin.

- **Females** capable of becoming pregnant should perform a pregnancy test before starting treatment with Iwilfin. You should use effective birth control methods during treatment with Iwilfin and for 1 week after the last dose.
- **Males** who have female partners capable of becoming pregnant should use effective birth control methods during treatment with Iwilfin and for 1 week after the last dose.

Breastfeeding

Do not use the medicine without consulting your doctor if you are breastfeeding or plan to breastfeed. It is not known if Iwilfin passes into breast milk, how it affects the breastfed baby or milk production. The risk of serious side effects cannot be excluded, therefore you should not breastfeed during treatment with Iwilfin and for one week after the last dose.

Driving and using machines

Iwilfin may slightly affect your ability to drive or use machines. The reason for this is that Iwilfin may cause side effects such as tiredness.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The dosage ranges from one tablet per dose (192 mg) to four tablets per dose (768 mg), based on the body surface area. Your doctor will calculate your body surface area once every 3 months.

Your doctor may change the dosage depending on your side effects.

Take Iwilfin twice a day with or without food.

The treatment duration will be determined by your doctor only.

Do not exceed the recommended dose.

Swallow the tablets whole. If you cannot swallow the tablets whole, they can be chewed, or crushed and mixed with soft food or liquid.

If you are crushing Iwilfin tablets:

- They can be mixed with 2 tablespoons of soft food or liquid.
- Swallow the entire mixture.
- Inspect the container to verify that the entire content has been swallowed. If any crushed tablet pieces remain, mix them with another small amount (about 2 tablespoons) of soft food or liquid.
- It is advisable to take the entire mixture immediately after preparation, and in any case no later than 1 hour of mixing. Discard any mixture residues left after 1 hour.

If you have accidentally taken a higher dose

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take it as soon as you remember. If it is 7 hours or less until your next dose, skip the forgotten dose and take your next dose at the regular time.

If you vomit after taking a dose, do not take an extra dose. Take your next dose at the regular time.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Iwilfin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

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 (myelosuppression, anemia, or infection). See section 'Tests and follow-up'. **Tell your doctor immediately** if you develop symptoms of low blood cell counts, including:
 - fever (38°C or higher)
 - easy bruising or bleeding
 - blood in the urine or stool
 - feeling unusually tired or weak
 - shortness of breath
 - chills or shivering

- **Liver problems**, including changes in liver enzymes and elevated bilirubin values. See section 'Tests and follow-up'. **Tell your doctor immediately** if you develop symptoms of liver problems, including:
 - yellowing of your skin and the white parts of your eyes (jaundice)
 - dark or "tea-colored" urine
 - light-colored stools (bowel movements)
 - nausea or vomiting
 - easy bruising or bleeding
 - lack of appetite
 - pain or tenderness on the right side of the abdominal area
- **New or worsening hearing loss.** Hearing loss is very common during treatment with Iwifin and can be serious. See section 'Tests and follow-up'. Some people have needed to use hearing aids. Tell your doctor immediately if you experience ringing in your ears, or any new or worsening hearing loss.

Additional side effects

Very common side effects - affect more than one in ten users

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

Common side effects - affect 1–10 in 100 users

- skin infection
- urinary tract infection
- abnormal blood test results:
 - blood chemistry: increased liver enzymes, increased alkaline phosphatase, potassium, glucose. Decreased sodium, glucose, potassium.
 - hematology: decreased neutrophils, hemoglobin, white blood cells, platelets.

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- rash
- extremity pain
- alopecia

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an

online form for reporting side effects, or you can also use this link:
<https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C. Excursions are permitted in the range of 15°C-30°C.

Shelf life after opening: 50 days. After opening, store below 25°C.

Do not discard the medicine via wastewater or household waste. Ask the pharmacist how to dispose of this medicine (medicines you no longer use) to help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Silicified microcrystalline cellulose, partially pregelatinized maize starch, colloidal silicon dioxide, magnesium stearate.

What the medicine looks like and contents of the pack:

Round, white to off-white tablets imprinted with EFL on one side and 192 on the other side.

lwilfin is available in bottle packs containing 100 tablets. Child resistant packaging.

The pack contains a desiccant. Do not swallow or remove it from the bottle.

Registration holder's name and address: MBI Pharma Ltd., P.O. Box 5061, Kadima.

Manufacturer's name and address: USWM, LLC, 4441 Springdale Road, Louisville, KY 40241, USA

Approved in March 2025.

Registration number of the medicine in the Ministry of Health National Drug Registry:

178-62-38022-99