

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

Ifinwil[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) below the dotted line has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Ifinwil?

Ifinwil contains the active ingredient eflornithine. Ifinwil is used to treat a type of cancer called “neuroblastoma”.

For more information, see Section [1. Why am I taking taking Ifinwil?](#) in the full CMI.

2. What should I know before I take Ifinwil?

Do not take if you have ever had an allergic reaction to eflornithine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

Your doctor will have your blood tested to check your full blood count and make sure your liver is working properly before you start taking Ifinwil.

Your doctor will have your hearing tested before you start taking Ifinwil.

For more information, see Section [2. What should I know before I take Ifinwil?](#) in the full CMI.

3. What if I am taking other medicines?

Talk to your doctor if you are taking any other medicines, or plan to take any other medicines.

4. How do I take Ifinwil?

Your doctor will work out how much you should take.

More instructions can be found in Section 4. [How do I take Ifinwil?](#) in the full CMI.

5. What should I know while taking Ifinwil?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist that you visit that you are taking Ifinwil.• Your doctor will continue to have your blood tested while you are taking Ifinwil.• Your doctor will continue to have your hearing tested while you are taking Ifinwil.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine without talking to your doctor.
Driving or using machines	<ul style="list-style-type: none">• Ifinwil may have a minor effect on your ability to drive or use machines because it may cause side effects such as fatigue.
Drinking alcohol	<ul style="list-style-type: none">• Drinking alcohol while taking Ifinwil is not recommended.
Looking after your medicine	<ul style="list-style-type: none">• Ifinwil should be stored at a temperature below 25°C.

For more information, see Section [5. What should I know while taking Ifinwil?](#) in the full CMI.

6. Are there any side effects?

Side effects that are common and serious include loss of hearing, problems balancing, fever, unexplained bruising, sudden bleeding, feeling very tired, weak or breathless.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ *This medicine is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.*

Ifinwil®

Active ingredient: *eflornithine*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Ifinwil. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Ifinwil.**

Where to find information in this leaflet:

- [1. Why am I taking Ifinwil?](#)
- [2. What should I know before I take Ifinwil?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Ifinwil?](#)
- [5. What should I know while taking Ifinwil?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Ifinwil?

Ifinwil contains the active ingredient **eflornithine**, which belongs to a group of medicines called ‘antineoplastic agents’.

Eflornithine suppresses cell growth of many cancer cells including neuroblastoma, a type of childhood cancer where early nerve cells grow out of control. Eflornithine is used after completion of high-risk neuroblastoma treatment to reduce the risk of the cancer coming back.

This medicine is used in adults and children with high-risk neuroblastoma that have responded to previous therapies.

2. What should I know before I take Ifinwil?

Warnings

Do not take Ifinwil if:

- you are allergic to eflornithine, or any of the ingredients listed at the end of this leaflet.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have not had a blood test and a hearing test before you start taking Ifinwil.

During treatment, you may be at risk of developing

certain side effects. It is important you understand these risks and how to look out for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Ifinwil could harm a developing baby. If you could become pregnant, or could get your partner pregnant, use highly effective contraception (such as condoms) while you’re taking Ifinwil and for a week after stopping it.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Ifinwil is not recommended during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ifinwil.

4. How do I take Ifinwil?

How much to take

Your doctor will work out how much you should take, based on your body surface area which is calculated by using your height and weight.

If it is too hard for you to swallow them, Ifinwil tablets can be chewed or crushed. Crushed tablets can be mixed with a small amount (about 2 tablespoons or 30mL) of soft food or room temperature liquid (e.g. water, clear soup, fruit, milk).

After taking the medicine, you need to check that all of it has gone. If any bits of tablet are left, mix this with a little more liquid or soft food and make sure that all the remaining particles are consumed.

Consume the mixture within 1 hour of mixing it up.

When to take Ifinwil

- Ifinwil should be taken twice a day, at the same time each day.

If you forget to take Ifinwil

Ifinwil should be taken regularly at the same times each day. If you forget a dose, take the dose as soon as you remember, unless the next dose is due within the next 7 hours, in which case the missed dose should be skipped.

If vomiting occurs after taking a dose, consider it skipped and just take the next scheduled dose. **Do not take a double dose to make up for the dose you missed.**

If you take too much Ifinwil

If you think that you have taken too much Ifinwil, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Ifinwil?

Things you should do

Your doctor will continue to have your blood tested and your hearing tested regularly while you are taking Ifinwil.

Call your doctor straight away if you:

- notice any hearing loss or problems balancing.
- notice any unexplained bruising or sudden bleeding
- notice blood in urine or stools
- or get a serious infection (with symptoms such as fever, chills or shivering, feeling breathless, feeling faint or weak, have a high heart rate or low blood pressure, nausea, vomiting, diarrhoea, headache, confusion or drowsiness)

Remind any doctor, dentist or pharmacist you visit that you are taking Ifinwil.

Things you should not do

- Do not stop taking this medicine without talking to your doctor.

Driving or using machines

Ifinwil may have a minor effect on your ability to drive or use machines. This is because Ifinwil can cause side effects such as fatigue.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol while taking Ifinwil is not recommended.

Looking after your medicine

- Keep the tablets in the bottle in the carton, until you are ready to take them.
- Ifinwil should be stored at a temperature below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot see or reach it.

When to discard your medicine

Do not take this medicine after the expiry date which is stated on the outer carton and on the bottle label,

after EXP. The expiry date refers to the last day of that month.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>Common:</p> <ul style="list-style-type: none"> • loss of hearing (new or worsening) • problems balancing • fever, chills • unexplained bruising • sudden bleeding • feeling very tired or weak, pale skin, weak or breathless, chills • Blood in urine or stools • Increase in liver enzymes (may cause symptoms such as fatigue, your skin or the white part of your eyes turns yellow (jaundice), dark or change in the colour of urine, change in colour of stools (bowel movement), loss of appetite, nausea and vomiting, feeling tired and weak, tenderness, easy bruising or bleeding longer than usual, pain or aching or tenderness on the right side of your stomach area) <p>Uncommon:</p> <ul style="list-style-type: none"> • infection of the skin (with symptoms such as tenderness, redness, pain, warmth or swelling of the skin around the injury) • problems sleeping • headache • diarrhoea and vomiting • nausea • rash or hives • middle ear infection • rash with a mixture of raised bumps and flat patches, itching • tiredness <p>Blood test results:</p> <ul style="list-style-type: none"> • low red blood cells (anaemia) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • low neutrophils (blood cells that fight infection) • low platelets (clotting cells) • low blood sugar levels • low potassium levels 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you have experienced, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ifinwil contains

Active ingredient (main ingredient)	eflornithine
Other ingredients (inactive ingredients)	Silicified microcrystalline cellulose, pregelatinized maize starch, silicon dioxide, magnesium stearate

Do not take this medicine if you are allergic to any of these ingredients.

What Ifinwil looks like

Ifinwil tablets are white, round, biconvex tablets with 'EFL' on one side and '192' on the other side. Ifinwil is available in packs of 100 in an outer carton with a white high density polyethylene bottle, containing a silica gel desiccant and polyester coil.

(AUST R 445692).

Who distributes Ifinwil

Norgine Pty Ltd
 Suite 3.01, Building A
 20 Rodborough Road
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 Australia
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