

OXALATIN®

oxaliplatin powder for injection 50mg and 100mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OXALATIN injection. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of using OXALATIN against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet as you may need to read it again.

What OXALATIN is used for

OXALATIN is used to treat cancer of the large intestine and rectum (colorectal cancer). OXALATIN is used with two other anti-cancer drugs, fluorouracil (FU), and folinic acid. The active ingredient in OXALATIN is called oxaliplatin.

Cancer cells have changed from normal cells so that they grow in an uncontrolled way. Oxaliplatin works by interfering with cancer cell growth. Because of the similarities between cancer cells and normal cells, anti cancer drugs often have unwanted effects on the body.

Your doctors have decided to treat you with OXALATIN because they believe that the benefit of OXALATIN treatment will be greater than the unwanted effects.

Many of the side effects from anti cancer drugs are predictable and can be prevented or lessened. Your doctor and other staff will take all of the precautions needed to reduce the unwanted effects of treatment.

OXALATIN is only available on a prescription from your doctor.

Before you are given OXALATIN

When you must not receive it

You should not be given OXALATIN if you are allergic to the active ingredient 'oxaliplatin'.

If you have had an allergic reaction to oxaliplatin before, you should not receive it again.

You must not receive OXALATIN if you are pregnant or breastfeeding.

Oxaliplatin may cause birth defects if you are being treated with it at the time of conception or it is given to women who are already pregnant. Adequate contraception is required during treatment with oxaliplatin. You should discuss this with your doctor. Nursing mothers are advised not to breastfeed while receiving oxaliplatin, as the effect of breast milk from such patients is unknown.

You must not receive OXALATIN if you have severe kidney disease.

What you should tell your doctor

You must tell your doctor if:

- you have had a reaction to any other platinum compound
- you have severe kidney disease
- you have nerve damage (neuropathy)
- you have any other medical condition that he or she is not aware of
- you are taking any other medicines, including medicines that you have bought without a prescription from a pharmacy, supermarket or health food shop.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How OXALATIN is given

OXALATIN will be given to you as an infusion into one of your veins (this is called an intravenous infusion). The infusion will be given over 2-6 hours.

The dose of OXALATIN is calculated according to your body surface area, which is calculated from your weight and height. The usual dose is 85mg/m² every two weeks. Your doctor may change the dose in some circumstances.

Each course of treatment is called a cycle; your doctor will tell you how many cycles you will receive.

OXALATIN will be used with fluorouracil (FU) and folinic acid.

OXALATIN is not recommended in children.

While you are being given OXALATIN

Things you must do

Avoid cold foods and drinks and cover skin prior to exposure to cold during or within 48 hours following being given oxaliplatin, since neurological effects may be brought on or worsened by exposure to cold.

Contact your doctor immediately if you develop fever, particularly in association with persistent diarrhoea or evidence of infection since this may indicate low blood count.

Contact your doctor if persistent vomiting, diarrhoea, signs of dehydration, cough or breathing difficulties or signs of allergic reaction occur.

Be aware that this medication may affect your vision, which may impair your ability to drive and use machines.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while OXALATIN is being given to you. You should also tell your doctor if you do not feel well between courses of OXALATIN.

All medicines can have side effects. It is important to understand the side effects that OXALATIN may cause, even though you may not experience them. As well as the predictable side effects of OXALATIN, there are other effects that occur much more rarely.

If you have any side effects or notice anything unusual it is important to inform your doctor before your next treatment.

Your doctor will decide whether such effects are because of your treatment, and what action needs to be taken.

This section explains the side effects of OXALATIN, and some of the checks made before each treatment to prevent excessive side effects.

- **Physical Condition.** Before each treatment with OXALATIN you will be examined for any condition that may be affected by chemotherapy (for example, infection, or loss of feeling). This will include those conditions caused by previous treatment, those caused by your disease, and those caused by other things.
- **Loss of feeling.** OXALATIN can affect nerves in the hands and feet. This is common soon after treatment and can appear as tingling or numbness in the fingers or toes, and may be made worse by cold temperatures or by contact with cold water or other cold objects. These symptoms often go away between treatments, but may last longer and get worse with repeated treatment. In some patients the limbs may become weak or painful. However, in most patients these symptoms improve after treatment is stopped. Tell your doctor if any of these things happen. Your doctor will examine you before treatment to see if you are affected.
- **Nausea and Vomiting.** Severe nausea and vomiting is uncommon with OXALATIN. Mild nausea and vomiting is more common. Medication to prevent the sickness caused by OXALATIN will be given before treatment, and may sometimes be continued after treatment.
- **Diarrhoea.** Severe diarrhoea may occur during treatment with OXALATIN.

If you suffer from persistent or severe diarrhoea or vomiting, contact your doctor urgently for treatment advice.

- **Low Blood Counts.** OXALATIN can affect the body's ability to make blood cells. There are three types of blood cells checked before each treatment; platelets, which help control bleeding; white blood cells, which help fight infection; and red blood cells which move oxygen around the body. If your blood count is too low, your treatment may be postponed, or the dose reduced. Tell your doctor if you notice any bruising or abnormal bleeding, or have an infection. These may be signs of a low blood count.
- **Difficulty swallowing.** Some patients may experience a sudden, temporary feeling of difficulty with swallowing or breathing. This sensation, if it occurs, usually happens during the infusion or within hours after the infusion. It may be triggered by swallowing a cold drink. Although unpleasant, this feeling does not last long, and goes away by itself. Tell your doctor if this happens to you.

Other known side effects of OXALATIN include:

- mucositis (sore lips or mouth ulcers)
- abdominal pain
- constipation
- anorexia
- changes to liver function
- mild hair loss (alopecia)
- fever
- inflammation around the injection site
- tiredness
- skin rash
- allergic reactions
- conjunctivitis
- altered taste
- abnormal tongue sensation
- nose bleeds
- feeling of chest pressure

- hiccups
- voice disturbance (rare)
- loss of hearing (rare)
- lung disorders (rare)
- visual disturbance (rare)

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

If you receive too much (overdose)

Your doctor will decide what dose of OXALATIN you need, and this will be given under close supervision, usually in a hospital setting. The risk of an overdosage in these circumstances is low. In the event of an overdose occurring, your doctor will decide on the treatment necessary.

Storage

If you need to store OXALATIN before you take it with you to hospital, make sure it is stored in a cool dry place where the temperature does not exceed 25°C. Protect from light.

Do not use it after the expiry date printed on the vial.

Product description

OXALATIN comes in a powder in a glass vial. Each OXALATIN vial contains the active ingredient, oxaliplatin 50mg or 100mg. Besides the active ingredient, OXALATIN powder for injection also contains mannitol.

Australian Registration Numbers:

OXALATIN (oxaliplatin 50mg)
powder for injection: AUST R
126124

OXALATIN (oxaliplatin 100mg)
powder for injection: AUST R
126125

Sponsor

OXALATIN is supplied in Australia
by:

Spirit Pharmaceuticals Pty Ltd
117 Harrington Street
The Rocks Sydney NSW 2000
Australia

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