
Consumer Medicine Information

March 2009

Oxaliplatin Actavis[®]

Oxaliplatin Actavis 50 (oxaliplatin 50mg power for injection vial)

Oxaliplatin Actavis 100 (oxaliplatin 100mg power for injection vial)

What is in this leaflet?

This leaflet answers some common questions about Oxaliplatin Actavis Powder for injection. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of using Oxaliplatin Actavis 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 want to read it again.

What Oxaliplatin Actavis is used for

Oxaliplatin Actavis is used to treat cancer of the large intestine and the rectum (colorectal cancer). It is used with two other anti-cancer drugs, fluorouracil (FU) and folinic acid.

Oxaliplatin Actavis contains the active ingredient, 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

Oxaliplatin Actavis because they believe that the benefit of Oxaliplatin Actavis treatment will be greater than the unwanted effects. Many of the side effects from anti cancer drugs are predictable and can be prevented and lessened.

Your doctor and other staff will take all of the precautions needed to reduce the unwanted effects of treatment.

Oxaliplatin Actavis is available only with a doctor's prescription.

Before you are given Oxaliplatin Actavis

When you must not receive it
You should not be given Oxaliplatin Actavis if you are

<ul style="list-style-type: none"> allergic to the active ingredient, oxaliplatin. 	What you should tell your doctor	How Oxaliplatin Actavis is given
<p>If you have had an allergic reaction to oxaliplatin before, you should not receive it again.</p> <ul style="list-style-type: none"> pregnant or breastfeeding. <p>Oxaliplatin may cause birth defects if you are being treated with it at the time of conception or if is given to women who are already pregnant. Adequate contraception is required during treatment with oxaliplatin. You should discuss this with your doctor.</p> <p>Nursing mothers are advised not to breastfeed while receiving oxaliplatin, as the effect of breast milk from such patients is unknown.</p>	<p>You must tell your doctor if:</p> <ul style="list-style-type: none"> You have had a reaction to any other platinum compound You have serve 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. 	<p>Oxaliplatin Actavis 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 Oxaliplatin Actavis is calculated by your doctor. Each course of treatment is called a cycle; your doctor will tell you how many cycles you will receive. Oxaliplatin Actavis will be used with fluorouracil (FU) and folinic acid.</p> <p>Oxaliplatin Actavis is not recommended in children.</p>
<ul style="list-style-type: none"> have severe kidney disease. Have nerve damage(peripheral sensory nerve damage 	<p>Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.</p> <ul style="list-style-type: none"> You are pregnant or breastfeeding 	<p>While you are being given Oxaliplatin Actavis</p> <p>Things you must do</p> <ul style="list-style-type: none"> Avoid cold foods and drinks 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.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well while Oxaliplatin Actavis is

being given to you. You should also tell your doctor if you do not feel well between courses of Oxaliplatin Actavis.

All medicines can have side effects. It is important to understand the side effects that Oxaliplatin Actavis may cause, even though you may not experience them. As well as the predictable side effects of Oxaliplatin Actavis, 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 Oxaliplatin Actavis, and some of the checks made before each

treatment to prevent excessive side effects.

- *Physical Condition:* Before each treatment with Oxaliplatin Actavis 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:* Oxaliplatin Actavis 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. *vomiting, contact your doctor urgently for treatment advice.* does not last long, and goes away by itself.

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 Oxaliplatin Actavis. Mild nausea and vomiting is more common.

Medication to prevent the sickness caused by Oxaliplatin Actavis will be given before treatment, and may sometimes be continued after treatment.

• *Diarrhoea:* Severe diarrhoea may occur during treatment with Oxaliplatin Actavis.

If you suffer from persistent or severe diarrhoea or

• *Low Blood Counts:* Oxaliplatin Actavis can affect the body's ability to make blood cells. 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 injection or within hours after the infusion. It may be triggered by swallowing a cold drink. Although unpleasant, this feeling

Tell your doctor if this happens to you.

Other known side effects of Oxaliplatin Actavis include:

- mucositis (sore lips or mouth ulcers)
- abdominal pain
- mild hair loss (alopecia)
- fever
- inflammation around the injection site
- tiredness
- skin rash
- allergic reactions
- Infection
- altered taste
- abnormal tongue sensation
- nose bleeds
- feeling of chest pressure
- voice disturbance (rare)
- loss of hearing (rare)
- lung disorders (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 Oxaliplatin Actavis you need, and this will be given under close supervision, usually in a hospital setting. The risk of an over dosage 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 Oxaliplatin Actavis 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.

This is not all the information that is available on Oxaliplatin Actavis. If you have any more questions or are not sure about anything ask your doctor or pharmacist.

Product Description

Oxaliplatin Actavis Powder for injection contains 50 mg or 100 mg oxaliplatin and looks like a compact mass or white or almost white fragments with porous appearance.

Oxaliplatin Actavis has to be diluted with water for injections before use. It also contains lactose.

Sponsor

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South Australia 5006
ABN 43 122 896 468
Phone Number: 1300 881 893

Distributor in Australia:

Solely distributed in Australia by:
Generic Health Pty Ltd.,
Suite 1, 1175 Toorak Road,
Camberwell VIC 3124.

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