OXALIPLATIN ACCORD

Oxaliplatin Concentrated Injection 50 mg/10 mL and 100 mg/20 mL

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given this medicine.

This leaflet answers some common questions about Oxaliplatin Accord.

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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with this medicine.
You may need to read it again.

What Oxaliplatin Accord is used for

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

Cancer cells are normal cells which have changed 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 Accord because they believe that the benefit of Oxaliplatin Accord 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.

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

Before you are given Oxaliplatin Accord

When you must not be given it

You should not be given Oxaliplatin Accord 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 be given Oxaliplatin Accord 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 be given it 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 Oxaliplatin Accord is given

Oxaliplatin Accord 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 Accord is calculated according to your body surface area, which is calculated from your weight and height. The usual dose is 85 mg/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.

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

Oxaliplatin Accord is not recommended in children.

While you are using Oxaliplatin Accord

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.

Visual disturbance is a rare side effect of Oxaliplatin Accord. Contact your doctor if this happens to you, and do not drive or use machinery until your vision is clear.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well while Oxaliplatin Accord is being given to you.

You should also tell your doctor if you do not feel well between courses of Oxaliplatin Accord.

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

- *Physical Condition*. Before each treatment with Oxaliplatin Accord 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 Accord 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 Oxaliplatin Accord. Mild nausea and vomiting is more common. Medication to prevent the sickness caused by Oxaliplatin Accord will be given before treatment, and may sometimes be continued after treatment.
- *Diarrhoea*. Severe diarrhoea may occur during treatment with Oxaliplatin Accord.

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

- *Low Blood Counts*. Oxaliplatin Accord 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 Oxaliplatin Accord are:

- 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
- 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 Oxaliplatin Accord 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

Store below 25°C. Protect from light. Do not freeze.

Shelf life after dilution

After dilution in 5% glucose, chemical and physical in-use stability has been demonstrated for up to 48 hours at 2°C to 8°C and for 24 hours at 25°C.

From a microbiological point of view, the infusion preparation should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C unless dilution has taken place in controlled and validated aseptic conditions.

Special precautions for administration

- DO NOT use injection equipment containing aluminium.
- DO NOT administer undiluted.
- DO NOT mix or administer with sodium chloride injection or any other solution containing chlorides
- DO NOT mix with any other medication or administer simultaneously by the same infusion line (in particular fluorouracil and folinic acid). A Y-tube may be used (see Infusion)
- USE ONLY the recommended diluents (see below).
- Any diluted solution that shows evidence of precipitation should not be used and should be destroyed.

Preparation of Infusion Solution

Dilution before Infusion

Oxaliplatin injection MUST be further diluted in an infusion solution of 250-500 mL of 5% glucose injection. From a microbiological and chemical point of view, this infusion preparation should be used immediately. Inspect visually prior to use. Only clear solutions without particles should be used. The product is for single use in one patient only. Discard any residue. NEVER use sodium chloride solution for dilution.

Infusion

The administration of oxaliplatin does not require prehydration. Oxaliplatin diluted in 250 to 500 mL of a glucose 5% injection must be infused either by central venous line or peripheral vein over 2 to 6 hours. When oxaliplatin is administered with fluorouracil, the oxaliplatin infusion should precede that of fluorouracil.

Oxaliplatin can be co-administered with folinic acid infusion using a Y-tube placed immediately before the site of injection. The drugs should not be combined in the same infusion bag. Folinic acid must be diluted using isotonic infusion solutions such as 5% glucose solution but NOT sodium chloride solutions or alkaline solutions.

Flush the line after oxaliplatin administration.

While oxaliplatin has minimal to no vesicant potential, extravasation may result in local pain and inflammation which may be severe and lead to complications especially when oxaliplatin is infused through a peripheral vein. In case of oxaliplatin extravasation, the infusion must be stopped immediately and the usual local symptomatic treatment initiated.

Disposal

All materials that have been used for dilution and administration must be destroyed according to local statutory requirements

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

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

Product Description

What it looks like

Oxaliplatin Accord comes as a concentrated solution in a glass vial.

Pack size: 1 vial.

Ingredients

Each Oxaliplatin Accord vial contains the active ingredient, oxaliplatin 50 mg or 100 mg.

Beside the active ingredient Oxaliplatin Accord concentrated injection contains lactose monohydrate and water for injections.

Name and Address of the Sponsor

Accord Healthcare Pty Ltd
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Melbourne, VIC, 3000
Australia

Australian Registration Numbers

50 mg/10 mL: AUST R 209719
100 mg/20 mL: AUST R 209720

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