

CONSUMER MEDICINE INFORMATION

OXALICCORD

Oxaliplatin concentrated solution for infusion

Please read this leaflet before you are given this medicine.

What is in this leaflet

This leaflet answers some common questions about OXALICCORD.

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 OXALICCORD is used for

OXALICCORD is used to treat cancer of the large intestine and rectum (colorectal cancer). OXALICCORD is used with two other anti-cancer drugs, fluorouracil (FU), and folinic acid. The active ingredient in OXALICCORD 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 OXALICCORD because they believe that the benefit of OXALICCORD 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.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor or pharmacist if you have any questions about why this medicine has been prescribed for you.

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

Before you are given OXALICCORDER***When you must not be given it***

You should not be given OXALICCORDER 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 OXALICCORDER 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.

Do not use it after the expiry date (EXP) printed on the vial. If you are given this medicine after the expiry date has passed, it may not work as well.

Before you start are given it

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.

Taking other medicines

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

Some medicines and OXALICCORDER may interfere with each other.

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

How OXALICCORDER is given

OXALICCORDER 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 OXALICCORDER 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 or 130mg/m² every three 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.

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

OXALICCORDER is not recommended in children.

If you receive too much (overdose)

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

While you are using OXALICCORDER

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 OXALICCORDER. 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 OXALICCORDER is being given to you.

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

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

- *Physical Condition.* Before each treatment with OXALICCORDER 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.* OXALICCORD 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 OXALICCORD. Mild nausea and vomiting is more common. Medication to prevent the sickness caused by OXALICCORD will be given before treatment, and may sometimes be continued after treatment.

- *Diarrhoea.* Severe diarrhoea may occur during treatment with OXALICCORD.

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

- *Low Blood Counts.* OXALICCORD 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 OXALICCORD 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.

After using OXALICCORD

Storage

If you need to store OXALICCORD before you take it with you to hospital, make sure that it is stored in a cool dry place where the temperature does not exceed 25°C. Keep the vial in the outer carton in order to protect from light. Do not freeze.

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

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

Shelf life

2 years

Shelf life after dilution

After dilution of the solution in 5% glucose solution, 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.

Inspect visually prior to use. Only clear solutions without particles should be used. The medicinal product is for single use only. Any unused solution should be discarded.

Special precautions for administration

DO NOT use any injection material 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 reconstituted solution that shows evidence of precipitation should not be used and should be destroyed.

Preparation of Infusion Solution Dilution before Infusion

The reconstituted solution **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 either reconstitution or 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 reconstitution, for dilution and administration must be destroyed according to local statutory requirements

Product description**What it looks like**

OXALICCORD comes as a concentrated solution in a glass vial.

A box contains 1 vial.

Ingredients

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

Beside the active ingredient - OXALICCORD concentrated solution for injection contains Lactose and water for injections.

Supplier

Distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Ltd.
PO Box 128244.
Remuera, Auckland
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