

OXALIPLATIN ACCORD

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Oxaliplatin Accord?

Oxaliplatin Accord contains the active ingredient oxaliplatin. Oxaliplatin Accord is used to treat cancer of the large intestine and rectum (colorectal cancer). It is used in combination with other anti-cancer drugs; fluorouracil and folinic acid. Oxaliplatin Accord is not recommended in children.

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

2. What should I know before I am given Oxaliplatin Accord?

Do not use if you have ever had an allergic reaction to Oxaliplatin, any of the ingredients listed at the end of the CMI or other platinum compound.

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.

For more information, see Section [2. What should I know before I am given Oxaliplatin Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines and Oxaliplatin may interfere with each other and may affect how well each medicine works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Oxaliplatin Accord?

Oxaliplatin Accord will be given to you by a doctor or a nurse as an infusion into one of your veins.

More instructions can be found in Section [4. How will I be given Oxaliplatin Accord?](#) in the full CMI.

5. What should I know while being given Oxaliplatin Accord?

Things you should do	<ul style="list-style-type: none">• Be sure to keep all your doctor's appointments• Tell your doctor if you do not feel well between courses of oxaliplatin• If you suffer from persistent or severe diarrhoea or vomiting, contact your doctor urgently for treatment advice• Tell your doctor if you notice any bruising or abnormal bleeding• Avoid cold foods and drinks and cover skin prior to exposure to cold during or within 48 hours following being given oxaliplatin• Tell your doctor immediately if you become pregnant while you are being given oxaliplatin
Driving or using machines	Be careful driving or operating machinery until you know how Oxaliplatin Accord affects you. 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.

For more information, see Section [5. What should I know while being given Oxaliplatin Accord?](#) in the full CMI.

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.

Some of the very serious side effects are:

- allergic reactions - swelling of the face, lips, mouth, tongue or throat; a wheezing or whistling sound when inhaling; difficulty breathing; shortness of breath and looking pale; rash, itching or hives on the skin
- chest pain or feeling of chest pressure
- coughing
- abnormal changes to your heart rate
- feeling lightheaded or dizzy
- breakdown of muscle tissue causing muscle fibres to be released into the blood. Symptoms include dark, red urine, decreased urine output, muscle stiffness or aching
- serious lung infections. Symptoms include fever, chills, shortness of breath, and a cough which produces yellow-green phlegm and occasionally blood
- convulsions, fits or seizures
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea

Tell your doctor immediately even if they occur even if this is several months or years after stopping treatment with Oxaliplatin Accord.

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.

OXALIPLATIN ACCORD

Active ingredient(s): Oxaliplatin

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I being given Oxaliplatin Accord?](#)
- [2. What should I know before I am given Oxaliplatin Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Oxaliplatin Accord?](#)
- [5. What should I know while being given Oxaliplatin Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Oxaliplatin Accord?

Oxaliplatin Accord contains the active ingredient oxaliplatin. 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 and folinic acid.

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.

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

2. What should I know before I am given Oxaliplatin Accord?

Warnings

You must not be given Oxaliplatin Accord if:

- you have an allergy to oxaliplatin, any of the ingredients listed at the end of this leaflet or other platinum compound
- you have a blood disorder with a reduced number of platelets or white blood cells

- you have nerve damage such as numbness or weakness of the arms or legs (neuropathy)
- you have severe kidney disease
- you are pregnant or breastfeeding

Check with your doctor if you have or have had:

- a reaction to any other platinum compound
- severe kidney disease
- nerve damage (neuropathy)
- any other medical condition that your doctor is not aware of

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use Oxaliplatin Accord if you are pregnant. 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.

Tell your doctor or pharmacist if you or your partner are pregnant or intend to become pregnant.

Nursing mothers are advised not to breastfeed while receiving oxaliplatin, as the effect of breast milk from such patients is unknown.

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 Oxaliplatin Accord.

4. How will I be given Oxaliplatin Accord?

How much will be given

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 and folinic acid.

Oxaliplatin Accord is not recommended in children.

How it 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.

If you receive too much Oxaliplatin Accord

Since Oxaliplatin Accord is usually given to you in hospital under the supervision of your doctor or nurse, it is very unlikely that you will be given too much of the medicine. If you think that you have been given too much Oxaliplatin Accord.

You should immediately:

- contact your doctor or nurse
- phone the Poisons Information Centre (**by calling 13 11 26**)

5. What should I know while being given Oxaliplatin Accord?

Things you must do

Keep all of your doctor's appointments so your progress can be checked.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given Oxaliplatin Accord.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Oxaliplatin Accord.

If you become pregnant while you are being given Oxaliplatin Accord, tell your doctor immediately.

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 (such as numbness or weakness of the arms and legs or, difficulty swallowing) 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.

Tell your doctor if you notice any bruising or abnormal bleeding, or have an infection. These may be signs of a low blood count.

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

Driving or using machines

Be careful driving or operating machinery or doing jobs that require you to be alert until you know how Oxaliplatin Accord affects you.

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.

Looking after your medicine

The hospital will store Oxaliplatin Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Oxaliplatin Accord that may be left over.

Do not use this medicine after the expiry date.

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.

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 feel unwell between courses of Oxaliplatin Accord. If you have any side effects or notice anything unusual it is important to inform your doctor before your next treatment.

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

Some of the checks made before each treatment to prevent excessive side effects are:

- 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.

- 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.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> • abdominal pain • constipation • anorexia • mild hair loss (alopecia) • inflammation around the injection site • tiredness or unusual weakness • conjunctivitis • runny or blocked nose • altered taste • nose bleeds • voice disturbance (rare) • loss of hearing (rare) • light headedness or dizziness • cough • hiccups • jaw spasm • high blood pressure • back pain • joint pain 	<p>Speak to your doctor if you have any of these common side effects and they worry you</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • sore lips or mouth • mouth ulcers • fever • skin rash or hives • abnormal tongue sensation • lung disorders (rare) • visual disturbance (rare) • infection in the body (symptoms include lightheadness, tiredness, fever, feeling unwell) • abnormal clotting followed by abnormal bleeding • duodenal stomach ulcer, which may cause abdominal pain • headaches or confusion, particularly if associated with visual disturbances 	<p>Call your doctor straight away if you have any of these side effects</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • allergic reactions - swelling of the face, lips, mouth, throat; a wheezing or whistling sound when inhaling; difficulty breathing; shortness of breath and looking pale; rash, itching or hives on the skin 	<p>Call your doctor straight away or go straight to the Emergency Department at</p>

Very serious side effects	What to do
<ul style="list-style-type: none"> • chest pain or feeling of chest pressure • coughing • abnormal changes to your heart rate • feeling lightheaded or dizzy • breakdown of muscle tissue causing muscle fibres to be released into the blood. Symptoms include dark, red urine, decreased urine output, muscle stiffness or aching • serious lung infections. Symptoms include fever, chills, shortness of breath, and a cough which produces yellow-green phlegm and occasionally blood • convulsions, fits or seizures • vomiting blood or material that looks like coffee grounds • bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea 	<p>your nearest hospital</p>

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Some of these side effects (for example, changes in liver or kidney function, changes in blood pressure, changes in blood glucose or calcium levels) can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed above may occur in some people. Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, 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 Oxaliplatin Accord contains

Active ingredient (main ingredient)	oxaliplatin
Other ingredients (inactive ingredients)	water for injections

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

What Oxaliplatin Accord looks like

Oxaliplatin Accord is a clear, colourless concentrated solution in a glass vial. (50 mg/10 mL: AUST R 352808, 100 mg/20 mL: AUST R 352809)

Who distributes Oxaliplatin Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

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