

DBL™ Oxaliplatin for Injection & DBL™ Oxaliplatin Concentrate

Oxaliplatin (ox-AL-ih-pla-tin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Oxaliplatin for Injection (oxaliplatin) and DBL™ Oxaliplatin Concentrate (oxaliplatin).

It does not contain all 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 you taking Oxaliplatin 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.

You may need to read it again.

What DBL™ Oxaliplatin is used for

Oxaliplatin belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

This medicine is used to treat cancers of the colon and rectum (colorectal cancer or bowel cancer).

It is often used in combination with other medicines (such as fluorouracil and folinic acid) to treat cancer.

Oxaliplatin works by killing cancer cells and/or stopping cancer cells from growing and multiplying. Because cancer cells are similar to normal cells, anti cancer drugs often have side effects on normal cells.

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

Ask your doctor if you have any questions about why DBL™ Oxaliplatin has been prescribed for you.

Your doctor may have prescribed it for another reason.

Oxaliplatin is not addictive.

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

There is not enough information to recommend the use of this medicine for children.

Before you are given DBL™ Oxaliplatin

When you must not take it

You should not be given DBL™ Oxaliplatin if you have had a reaction to any other platinum compound.

You should not be given DBL™ Oxaliplatin if you have an allergy to it or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Oxaliplatin may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin.

You should not receive DBL™ Oxaliplatin if you have, or have had, any of the following medical conditions:

- severe kidney disease

- nerve damage
- low blood count (white or red cells).

Tell your doctor if you are pregnant, intend to become pregnant.

Oxaliplatin may cause birth defects if you are being treated with it at the time of conception or it is given to you if you are already pregnant. Adequate contraception is required during treatment with Oxaliplatin. You should discuss this with your doctor.

Do not breast-feed if you are being treated with this medicine.

There is a possibility that your baby may be affected.

Do not take this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- you have had a reaction to any other platinum compound
- blood disease or any infections
- you have nerve damage (neuropathy)
- stomach ache or diarrhoea
- lung disease
- severe liver or kidney disease
- any other medical condition that they are not aware of.

If you have not told your doctor about any of the above, tell him/her before you start taking oxaliplatin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and oxaliplatin may interfere with each other.

This medicines may be affected by DBL™ Oxaliplatin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

Before each treatment with Oxaliplatin you will be examined for any condition that may be affected by chemotherapy (eg. 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.

How DBL™ Oxaliplatin is given

Oxaliplatin will be given to you as an infusion into one of your veins (this is called intravenous or IV infusion).

You may be given other drugs to help Oxaliplatin work. These drugs are:

- fluorouracil (another medicine used to treat cancer) and

- leucovorin (also called folinic acid)

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand these instructions, ask your doctor or pharmacist for help.

How much to take

The dose of Oxaliplatin is calculated according to your body surface area, which is calculated from your weight and height.

The usual dose is either 130 mg/m² every three weeks, or 85 mg/m² every two weeks. Your doctor may change the dose depending on your illness.

Ask your doctor if you want to know more about the dose of DBL™ Oxaliplatin you will be receiving.

How long to take it

The infusion will be given over 2-6 hours.

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

If you take too much (overdose)

Your doctor will decide what dose of DBL™ Oxaliplatin you need, and this will be given under close supervision, usually in a hospital. The risk of an over dosage in these circumstances is low. If you are given too much, your doctor will decide on the treatment necessary.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Oxaliplatin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are receiving DBL™ Oxaliplatin

Things you must do

Contact your doctor immediately if you develop a fever and persistent diarrhoea or an infection.

This may indicate you have a low blood count.

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DBL™ Oxaliplatin.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take DBL™ Oxaliplatin to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Avoid cold food and drinks, and cover your skin before exposure to cold during or within 48 hours following your dose of Oxaliplatin.

Neurological effects may be brought on or worsened by exposure to cold.

Be careful driving or operating machinery until you know how DBL™ Oxaliplatin affects you.

This medicine may cause nausea, tiredness, weakness or numbness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, side effects may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor immediately if you feel unexpected pain or discomfort during the infusion.

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

This medicine helps most people with cancer, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

- Sore lips or mouth ulcers
- Stomach pain or constipation
- Loss of appetite and weight loss
- Soreness around the injection site
- Tiredness
- Skin rash or allergic reactions
- Discharge or swelling with itching of the eyes and crusty eyelids (conjunctivitis)
- Altered taste

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Nausea and vomiting

- Mild hair loss (alopecia)
- Joint pain or back pain
- Fever
- Abnormal tongue sensations
- Nose bleeds
- Feeling of chest pressure
- Problems with talking
- Problems with hearing
- Problems with breathing

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- Loss of feeling
- Tingling or numbness in the hands or feet
- Weakness or pain in the arms or legs
- Severe diarrhoea
- Bruising or abnormal bleeding
- Infections

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- if you develop a fever with persistent diarrhoea or evidence of infection
- if you have persistent vomiting, diarrhoea, signs of dehydration, cough or breathing difficulties.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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

After using DBL™ Oxaliplatin

Storage

DBL™ Oxaliplatin for Injection will be stored in the pharmacy or on the ward. The injection is stored in a cool dry place where the temperature stays below 30°C.

DBL™ Oxaliplatin Concentrate will be stored in the pharmacy or on the ward. The injection is stored in a cool dry place where the temperature stays below 25°C. Protect from light.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

DBL™ Oxaliplatin for Injection comes as a powder in a glass vial.

Ingredients

DBL™ Oxaliplatin for Injection contains 50 mg or 100 mg of oxaliplatin as the active ingredient.

It also contains:

- lactose

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

DBL™ Oxaliplatin Concentrate comes as a sterile, preservative-free colourless or almost colourless solution in glass vials.

Ingredients

DBL™ Oxaliplatin Concentrate contains 50 mg/10 mL or 100 mg/20 mL of oxaliplatin as the active ingredient.

It also contains:

- tartaric acid
- sodium hydroxide
- water for injection

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer / Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Oxaliplatin for Injection is available in the following strengths:

- 50 mg AUST R 126111
- 100 mg AUST R 126112

DBL™ Oxaliplatin Concentrate is available in the following strengths:

- 50 mg /10 mL AUST R 131754
- 100 mg/20 mL AUST R 131758

This leaflet was updated in April 2014.