

DBL™ Oxaliplatin

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 treated with DBL Oxaliplatin?

DBL Oxaliplatin contains the active ingredient oxaliplatin. DBL Oxaliplatin is used to treat cancers of the colon and rectum (colorectal cancer or bowel cancer). For more information, see Section [1. Why am I being given DBL Oxaliplatin?](#) in the full CMI.

2. What should I know before treatment with DBL Oxaliplatin?

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

Talk to your doctor if you have any other medical conditions including severe kidney disease, nerve damage and low blood counts; 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 DBL Oxaliplatin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Oxaliplatin and affect how it works. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given DBL Oxaliplatin?

Your doctor will give you DBL Oxaliplatin as a slow injection (drip) into a vein and decide how much you will be given and for how long. You may also be given other drugs to help DBL Oxaliplatin work. More information can be found in Section [4. How am I given DBL Oxaliplatin?](#) in the full CMI.

5. What should I know while receiving DBL Oxaliplatin?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using DBL Oxaliplatin. • If you experience certain side effects, immediately inform your doctor so they can review your treatment. • Both males and females must use reliable contraception. • Avoid cold food and drinks, and cover your skin before exposure to the cold during or within 48 hours following your dose of DBL Oxaliplatin.
Things you should not do	• Do not breastfeed while being treated with DBL Oxaliplatin.
Driving or using machines	• DBL Oxaliplatin may cause nausea, tiredness, weakness, numbness or vision loss/disturbances in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	• Talk to your doctor if you drink alcohol.

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

6. Are there any side effects?

Side effects may include: Conjunctivitis; runny/blocked nose; weakness, fatigue; general or joint pain; hair loss; abnormal tongue sensations or taste; flushing; hiccups; sweating; nail problems; injection site redness, swelling, local pain; rash; constipation; loss of appetite, weight loss or gain; indigestion; nausea, vomiting.

Serious side effects may include: Allergic reaction; loss of feeling, paralysis; problems with palms of hands/soles of feet; depression; unusual/irregular heartbeat; mouth ulcers; chest pain/discomfort; inability to sleep; headache; changes in mental state; seizures; persistent vomiting; dehydration; bone pain; cough, breathing difficulties; fever, chills; signs of infection; persistent or severe diarrhoea; signs of infection; weakness or pain in the muscles, arms or legs; trouble swallowing, sore throat, jaw spasms; jaundice; light headedness, dizziness, fainting; visual disturbances; abnormal bruising or bleeding; severe stomach pain or cramping; dark coloured or little urine (wee).

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.

DBL™ Oxaliplatin

Active ingredient(s): *oxaliplatin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Oxaliplatin. **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 DBL Oxaliplatin.**

Where to find information in this leaflet:

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

1. Why am I being treated with DBL Oxaliplatin?

DBL Oxaliplatin contains the active ingredient **oxaliplatin**. DBL Oxaliplatin belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear these being called chemotherapy medicines.

DBL Oxaliplatin 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 needed to reduce the side effects of treatment.

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

Warnings

You should not be given DBL Oxaliplatin if:

- you are allergic to oxaliplatin, any other platinum compound or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
Symptoms of an allergic reaction to oxaliplatin may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin

- you have, or have had, any of the following medical conditions:
 - o severe kidney disease
 - o nerve damage
 - o low blood count (white or red blood cells, or platelets)
- you are pregnant or breastfeeding

Check with your doctor if you:

- have any other medical conditions, including:
 - o a history of reactions to any other platinum compound
 - o blood disease or any infections
 - o nerve damage (neuropathy)
 - o stomachache or diarrhoea
 - o lung disease
 - o heart problems
 - o liver or kidney disease
 - o plan to have any vaccinations
 - o any other medical condition that they are not aware of
- take any medicines for any other condition

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

DBL Oxaliplatin may affect fertility. Check with your doctor for advice on fertility preservation before you begin treatment. 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

Check with your doctor if you or your partner are pregnant or 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.
- Women of childbearing potential being treated with DBL Oxaliplatin should use effective contraception prior to and for at least 9 months after the last dose.
- Men being treated with DBL Oxaliplatin should use effective contraception prior to and for at least 6 months after the last dose if their female partner is of childbearing potential.

- Adequate contraception is required during treatment with DBL Oxaliplatin. You should discuss this with your doctor.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed.

- Do not breastfeed if you are being treated with DBL Oxaliplatin, and for three months after the last dose. There is a possibility that your baby may be affected.

Use in Children

Safety and effectiveness have not been established with use of DBL Oxaliplatin in children.

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.

Some medicines may interfere with DBL Oxaliplatin and affect how it works.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Oxaliplatin.

4. How am I given DBL Oxaliplatin?

How DBL Oxaliplatin is given

DBL Oxaliplatin is given as a single intravenous infusion (as a slow drip into a vein) over 2 to 6 hours.

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)

How much is given

Your doctor will decide how much DBL Oxaliplatin you should receive and the length of time (number of cycles) for which you should receive it.

If you are given too much DBL Oxaliplatin

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 dose in these circumstances is low. If you are given too much, your doctor will decide on the treatment necessary. If you experience any side effects, tell your doctor or nurse immediately.

If you think that you have been given too much DBL Oxaliplatin, you should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

5. What should I know while being treated with DBL Oxaliplatin?

Things you should do

- Avoid cold food and drinks, and cover your skin before exposure to the cold during or within 48 hours following your dose of DBL Oxaliplatin. Some side effects may be brought on or worsened by exposure to the cold.
- Tell the surgeon or anaesthetist that you are using this medicine if you are planning to have surgery. It may affect other medicines used during surgery.
- Tell your doctor you are taking this medicine if you are about to have any blood tests. 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.

Call your doctor straight away if you:

- develop a fever and persistent diarrhoea or signs of an infection (e.g. chills, sweats, sore throat, cough, a blocked nose etc.) or mouth ulcers. This may indicate you have a low blood count.
- develop persistent vomiting with diarrhoea, dehydration or thirst, cough or breathing difficulties or signs of an allergic reaction.
- develop tingling/numbness or weakness of the hands or feet or have trouble passing urine (wee)
- develop headache, altered mental functioning, seizures, hypertension, confusion, neurological disturbances and abnormal vision from blurriness to blindness.
- have unusual bruising or bleeding including blood in your urine (poo) or stool (poo)
- muscle pain and swelling combined with fever, weakness or dark urine (wee)
- have a sharp pain in your stomach that doesn't go away and blood in vomit or stool (poo)
- chest pain or fast/slow/irregular heartbeats
- become pregnant while being on this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using DBL Oxaliplatin.

Things to be careful of

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Oxaliplatin affects you.

DBL Oxaliplatin may cause nausea, tiredness, weakness, numbness or vision loss/disturbances in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Talk to your doctor if you drink alcohol.

Looking after your medicine

DBL Oxaliplatin will be stored at the hospital pharmacy or on the ward.

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.

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

Side effects

Side effects	What to do
Changes affecting your eyes, nose or mouth: - Discharge or swelling with itching of the eyes and crusty eyelids (conjunctivitis) - Abnormal tongue sensations - Altered taste - Runny or blocked nose Changes to your body: - Weakness or fatigue - General pain or joint pain - Hair loss (alopecia) - Flushing, hiccups, excessive sweating - Problems with nails - Redness, swelling and local pain at the site of your injection Changes to your skin: - Rash Changes to your digestive system: - Constipation - Loss of appetite and weight loss or weight gain - Indigestion, nausea or vomiting	Speak to your doctor or nurse if you have any of these side effects and they worry you.
Changes to your body:	Tell your doctor as soon as

Side effects	What to do
- Loss of feeling - Tingling, numbness, burning, itching, swelling, pain, peeling or blistering of the hands or feet - Rapid heart rate or irregular heartbeat - Sore lips or mouth ulcers - Back pain - Feeling of chest pressure - Inability to sleep Pain, discomfort or feeling unwell: - Headache - Diarrhoea - Weakness or pain in the muscles, arms or legs - Bone pain - Trouble swallowing, sore throat or heartburn or spasm of the jaw Changes to your mood: - Feelings of deep sadness, unworthiness or low mood	possible if you notice any of these side effects.
Changes to your body: - Sweating, fatigue, light-headedness, sudden dizziness or fainting. - Loss of balance and coordination, difficulty speaking, numbness or paralysis in the face, leg or arm. - Yellowish discolouration of the skin or eyeballs Pain, discomfort or feeling unwell: - Chest pain or discomfort which can spread to the arms, back, neck or jaw - Changes in mental state (confusion, thinking abnormal, altered consciousness) or seizures - Persistent vomiting, severe or persistent diarrhoea, signs of dehydration (e.g. feeling very thirsty, dry mouth, dark or very little wee), cough or breathing difficulties - Signs of infection - Fever, chills - Bruising or any abnormal bleeding, including blood in your poo (black tarry stools), blood in your wee or nose bleeds - Severe stomach pain, cramping, discomfort, fullness or swelling Changes to your vision:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Side effects	What to do
- Visual disturbances or loss of eyesight Changes when you go to the toilet: - Dark coloured wee (urine) or pain when weeing - Passing more, little or no wee.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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/safety/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 DBL Oxaliplatin contains

Active ingredient (main ingredient)	oxaliplatin
Other ingredients (inactive ingredients)	tartaric acid sodium hydroxide water for injection
Potential allergens	n/a

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

DBL Oxaliplatin does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Oxaliplatin looks like

DBL Oxaliplatin is a sterile, preservative-free colourless or almost colourless solution in a vial.

DBL Oxaliplatin is available in the following strengths:

- 100 mg/20 mL (AUST R 131758)

Who distributes DBL Oxaliplatin

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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