

CISPLATIN ACCORD

Cisplatin Solution for Injection 10 mg/10 mL, 25 mg/25 mL, 50 mg/50 mL and 100 mg/100 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cisplatin Accord.

It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Cisplatin Accord is used for

Cisplatin belongs to a group of anticancer medicines known as the platinum complexes. Cisplatin works by preventing the growth of cancer cells and eventually destroying them. It is used for cancer of the ovary, testis, bladder and also head and neck cancer.

Your doctor, however, may prescribe Cisplatin Accord for another purpose.

Ask your doctor, nurse or pharmacist if you have any questions about why Cisplatin Accord has been prescribed for you.

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

Cisplatin Accord is not addictive.

Before you are given it

When you must not be given it

Do not receive Cisplatin Accord if you have an allergy to cisplatin, carboplatin, other medicines containing platinum or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction 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;
- dizziness or light-headedness.

Do not receive Cisplatin Accord if you have, or have had, any of the following medical conditions:

- you have kidney disease or poor kidney function
- you have a low blood count
- you have hearing problems.

Do not receive it if you are pregnant or intend to become pregnant.

It may affect the developing baby.

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

Birth control should be used during treatment with cisplatin and for at least 26 weeks after you stop treatment (at least 31 weeks if have kidney disease). You must tell your doctor immediately if you think you are pregnant.

Males: Tell your doctor or pharmacist if your partner intends to become pregnant while

you are being given cisplatin, or shortly after you have stopped treatment.

It is recommended that you use effective contraception while you are using cisplatin and for at least 14 weeks after you stop treatment (at least 19 weeks if you have kidney disease). Cisplatin may have a prolonged effect on fertility in males and females. Your doctor should discuss this issue with you before you begin therapy with cisplatin.

Do not breastfeed if you are taking this medicine.

The possible harmful effects to the infant are unknown, so breastfeeding is not recommended while you are receiving cisplatin.

Do not receive it after the expiry date (EXP) printed on the carton.

If you receive it after the expiry date has passed, it may not work as well.

Do not receive it if the packaging is damaged or shows signs of tampering.

If you are not sure whether you should be receiving Cisplatin Accord, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

Like most medicines of this kind, cisplatin is not recommended to be

used during pregnancy. Your doctor will discuss the risks and benefits of being given it if you are pregnant.

Tell your doctor if you are breastfeeding or planning to breast-feed.

Your doctor will discuss the risks and benefits of being given it if you are breast-feeding or planning to breastfeed.

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

- kidney disease or poor kidney function
- a low blood count, abnormal or heavy bleeding
- hearing problems
- any sort of infection (e.g. sinusitis), tooth abscess, etc.
- abnormal or heavy bleeding
- bleeding gums
- unusual tiredness
- severe nausea and vomiting
- numbness or weakness of the arms and legs
- dizziness or being light-headed, especially on standing up
- problems with your sight
- fits
- muscle weakness
- a problem with blood clots forming in your blood vessels, such as painful inflammation of the veins (thrombophlebitis) or blockage of blood vessels in the legs (deep vein thrombosis or DVT), or lungs (pulmonary embolism).

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you are given Cisplatin Accord.

Taking other medicines or treatments

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you buy without a prescription from

your pharmacy, supermarket or health food shop.

Some medicines and cisplatin may interfere with each other. These include:

- other anticancer drugs, such as paclitaxel and ifosfamide
- antibiotics, such as aminoglycoside antibiotics, used to treat infection
- fluid tablets, such as loop diuretics, used to treat fluid build up
- lithium, used to treat bipolar disorder or schizophrenia
- anticonvulsants, used to treat seizures
- anticoagulants, used to prevent blood clots.

These medicines may be affected by cisplatin, or may affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you.

Do not have any immunisations (vaccinations) without your doctor's approval while you are being treated with cisplatin.

Your doctor, nurse or pharmacist has more information on medicines to be careful with or to avoid while being given Cisplatin Accord.

How it is given

Cisplatin Accord should only be administered by trained professionals, with appropriate handling, in a hospital or clinic environment.

Cisplatin Accord is for single use in one patient only. Any unused residue should be discarded.

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, age, blood

tests, how well your kidneys, liver and ears are working, and whether other medicines are being given at the same time.

Additional fluid is given before and after your dose of cisplatin. This is to make sure that you do not lose too much water and cause problems with your kidneys.

Ask your doctor if you want to know more about the dose of Cisplatin Accord you receive.

How it is given

Cisplatin Accord may be given as a single intravenous infusion or slow intravenous infusion.

If you receive too much (Overdose)

As Cisplatin Accord is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any unexpected or worrying side effects after being given Cisplatin Accord, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Symptoms of a cisplatin overdose include the side effects listed below in the 'Side Effects' section.

While you are being given it

Things you must do

Be sure to keep all your doctor's appointments.

Your doctor may also want to do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Tell all the doctors, dentists, and pharmacists who are treating you that you are being given Cisplatin Accord.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are being given Cisplatin Accord.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Cisplatin Accord.

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

Things to be careful of

Be careful when driving or operating machinery until you know how Cisplatin Accord affects you.

This medicine may cause dizziness, light-headedness or problems with movement in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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

If you drink alcohol dizziness or light-headedness may be worse.

Side Effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Cisplatin Accord.

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

- nausea or vomiting
- pain or redness at site of injection
- hair loss, especially of the scalp

- tiredness.

The above list includes the more common side effects of your medicine.

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

- muscle aches or pains
- bursts of pain that run down the back into the arms and legs
- hearing loss or ringing in the ears (tinnitus).

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

- flushing, swelling of the face, wheezing, fast heartbeat, a rash, dizziness or feeling light-headed
- fever and chills, sore throat, sweats or feel generally unwell
- blurred vision, changes in colour or blindness
- reduced urination, swelling of the feet or lower legs
- bleeding, unusual bruising, bleeding gums, blood in the urine or stools, or pinpoint red spots
- seizures, slurred speech and loss of taste and memory
- problems with movement or reduced reflexes, and leg weakness
- shaking or tremors, foot spasms
- muscle cramps or twitching
- paralysis or numbness of the face, arm or leg, tingling or a loss of sensation in the hands or feet
- irregular and/or rapid heart beat
- severe nausea or vomiting.

You may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell. Some side effects may only be seen by your doctor or nurse.

Other side effects not listed above may occur in some patients.

Ask your doctor to answer any questions you may have.

The benefits and side effects of Cisplatin Accord may take some time to occur. Therefore, even after you have finished your Cisplatin Accord treatment you should tell your doctor or nurse immediately if you notice any of the side effects listed in this section.

Storage

Cisplatin Accord injection solution will be stored in the pharmacy or on the ward. It must be kept in a cool dry place, protected from light, where the temperature stays below 25°C. It should not be refrigerated or frozen.

Product Description

What it looks like

Cisplatin Accord is a clear colourless to pale yellow solution in a glass vial.

Ingredients

Active Ingredient:
Cisplatin

Inactive ingredients:
Sodium chloride
Sodium hydroxide
Hydrochloric acid
Water for injections

Cisplatin Accord does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Name and Address of the Sponsor

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

Australian Registration Number

10 mg/10 mL: AUST R 286790

25 mg/25 mL: AUST R 286793

50 mg/50 mL: AUST R 286786

100 mg/100 mL: AUST R 286791

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