

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cisplatin 1 mg/ml Sterile Concentrate

cisplatin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cisplatin Sterile Concentrate is and what it is used for
2. What you need to know before you use Cisplatin Sterile Concentrate
3. How to use Cisplatin Sterile Concentrate
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1. What Cisplatin Sterile Concentrate is and what it is used for

Cisplatin forms part of a group of medicines called cytostatics, which are used in the treatment of cancer. Cisplatin can be used alone but more commonly Cisplatin is used in combination with other cytostatics.

What it is used for

Cisplatin can destroy cells in your body that may cause certain types of cancer (tumour of testis, tumour of ovary, tumour of the bladder, head and neck epithelial tumour, lung cancer and for cervical cancer in combination with radiotherapy).

2. What you need to know before you use Cisplatin Sterile Concentrate

Do not use Cisplatin Sterile Concentrate

- if you are allergic to cisplatin or to any of the other ingredients of this medicine (listed in section 6)
- if you have had hypersensitivity to similar anti-cancer medicines in the past
- if you have severe kidney disease
- if you have hearing difficulties
- if you have very low numbers of blood cells (called 'myelosuppression'), (your doctor will check this with a blood test)
- if you are dehydrated
- if you are pregnant or breast-feeding
- if you need to have a vaccine for 'yellow fever'

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Cisplatin Sterile Concentrate:

- if you have any symptoms of nerve damage (peripheral neuropathy) such as pins and needles, numbness or poor sense of touch
- if you have had radiation therapy to your head

- Cases of delayed-onset hearing loss have been reported in the paediatric population. Long term follow-up in this population is recommended

Other medicines and Cisplatin Sterile Concentrate

Tell your doctor or pharmacist if you are taking/ using, have recently taken/ used or might take/ use any other medicines, for example:

- some antibiotics, such as cephalosporins, aminoglycosides and amphotericin B and some substances used in medical imaging may make the side effects of cisplatin worse; particularly kidney problems
- some water tablets called loop diuretics, antibiotics called aminoglycosides and an anti-cancer medicine called ifosfamide may make the hearing loss side effect of cisplatin worse
- bleomycin (anti-cancer medicine), methotrexate (used to treat cancer or arthritis) and paclitaxel (anti-cancer medicine) may produce more side effects if cisplatin is also being used
- the effectiveness of oral anticoagulants such as coumarins/warfarin may be affected. Your doctor will monitor with blood tests
- use of certain antihistamines may hide the symptoms of balance changes (such as dizziness or tinnitus)
- the effectiveness of medicines used for the treatment of convulsions (e.g. phenytoin) may be reduced, so blood levels may need to be checked
- cisplatin may make the side effects of the anti-cancer medicine ifosfamide worse

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You must use reliable contraception during and for at least 29 weeks (at least 7 months) after the last dose.

Treatment with cisplatin can potentially cause permanent sterility in men.

Breast-feeding

Do not use this medicine if you are breast-feeding and for 4 weeks after treatment.

Fertility

Men with female partners of childbearing potential should be advised to use effective contraception during treatment with cisplatin and for at least 17 weeks (at least 4 months) after the last dose.

Both men and women should seek advice on fertility preservation before treatment.

Driving and using machines

Do not drive or use machines if you experience any side effect which may lessen your ability to do so.

Cisplatin Sterile Concentrate contains sodium

Cisplatin 10 mg/10 ml (1 mg/ ml) Sterile Concentrate for Solution for Infusion contains 35.4 mg of sodium (main component of cooking/table salt) in each 10 ml vial. This is equivalent to 1.8% of the recommended maximum daily dietary intake of sodium for an adult.

Cisplatin 50 mg/50 ml (1 mg/ml) Sterile Concentrate for Solution for Infusion contains 177 mg of sodium (main component of cooking/table salt) in 50 ml vial. This is equivalent to 8.9% of the recommended maximum daily dietary intake of sodium for an adult.

Cisplatin 100 mg/100 ml (1 mg/ ml) Sterile Concentrate for Solution for Infusion contains 354 mg of sodium (main component of cooking/table salt) in 100 ml vial. This is equivalent to 17.7% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine may be prepared with a solution that contains sodium. This should be taken into additional consideration if you are on a low salt (sodium) diet.

3. How to use Cisplatin Sterile Concentrate

Dosage and method of administration

Cisplatin should only be given by a specialist in cancer treatment.

The concentrate is diluted with a sodium chloride solution.

Cisplatin is only given by injection into a vein (an intravenous infusion).

Cisplatin should not come into contact with any materials that contain aluminium.

The recommended dosage of cisplatin depends on your well-being, the anticipated effect of the treatment, and whether or not cisplatin is given on its own (monotherapy) or in combination with other agents (combination chemotherapy).

Cisplatin (monotherapy):

The recommended dose is:

- a single dosage of 50 to 120 mg/m² body surface, every 3 to 4 weeks
- 15 to 20 mg/m² per day over a 5-day period, every 3 to 4 weeks

Cisplatin in combination with other chemotherapeutical agents (combination chemotherapy):

- 20 mg/m² or more, once every 3 to 4 weeks.

For treatment of cervical cancer cisplatin is used in combination with radiotherapy.

A typical dose is 40 mg/m² weekly for 6 weeks.

In order to avoid, or reduce, kidney problems, you are advised to drink copious amounts of water for a period of 24 hours following treatment with cisplatin.

If you use more Cisplatin than you should

Your doctor will ensure that the correct dose for your condition is given. In case of overdose, you may experience increased side effects. Your doctor may give you symptomatic treatment for these side effects. If you think you received too much cisplatin, immediately contact your doctor.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), flushing and you may feel you are going to faint

- severe chest pains possibly radiating to the jaw or arm with sweating, breathlessness and nausea (heart attack)
- pain or swelling at the injection site during the injection (may be due to the injection not going into the vein properly, which can lead to serious damage to the tissues around the injection site)
- stroke
- brain dysfunction (confusion, slurred speech, sometimes blindness, memory loss and paralysis)

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

Very common: may affect more than 1 in 10 people:

- decrease in bone marrow function (which can affect the production of blood cells)
- decrease in white blood cells, which makes infections more likely (leukopenia)
- decrease in blood platelets, which increases the risk of bruising and bleeding (thrombocytopenia)
- reduction of red blood cells which can cause weakness and your skin to look pale (anaemia)
- reduced level of sodium in the blood
- high temperature

Common: may affect up to 1 in 10 people:

- severe pain or swelling in either of your legs, chest pain, or difficulty breathing (possibly indicating harmful blood clots in a vein)
- fast, irregular or slow heart beats
- sepsis (blood poisoning)

Uncommon: may affect up to 1 in 100 people:

- severe allergic reaction (see above)
- damage to the ear (ototoxicity)
- reduced level of magnesium in the blood
- abnormal sperm production

Rare: may affect up to 1 in 1,000 people:

- increased risk of acute leukaemia
- seizures (fits)
- fainting, headache, confusion and loss of vision
- loss of certain types of brain function, including brain dysfunction characterised by spasms and reduced level of consciousness
- heart attack
- inflammation of mucous membranes of the mouth (stomatitis).
- peripheral neuropathy of the sensory nerves, characterised by tickling, itching or tingling without cause and sometimes with loss of taste, touch, sight, sudden shooting pains from the neck through the back and into the legs when bending forward

Very rare: may affect up to 1 in 10,000 people:

- heart arrest

Not known: frequency cannot be estimated from the available data:

- signs of infection such as fever or sore throat
- haemolytic anaemia
- inappropriate release of vasopressin hormone (ADH) which may lead to low sodium in the blood and water retention

- blood amylase (enzyme) increased
- dehydration
- reduced level of calcium, phosphate, potassium in the blood
- high level of uric acid in the blood
- muscle cramping
- spinal disease which may cause a sensation of electric shocks passing into your limbs
- loss of taste
- problems with your eyesight (blurred vision, odd colours, loss of vision or eye pain)
- ringing in the ears or deafness
- heart problems
- unusually cold or white hands and feet
- tingling, numbness or tremor in your hands, feet, arms or legs
- persistent headache
- feeling or being sick
- loss of appetite, anorexia
- hiccups
- diarrhoea
- liver enzymes increased, bilirubin increased
- difficulty breathing
- problems with your kidneys or urine
- hair loss
- rash
- extreme tiredness/weakness
- swelling or soreness where the injection was given
- cramps or spasms
- burning or prickling sensation
- unexpected bruising or bleeding
- haemolytic uremic syndrome which may cause changes to the kidneys and blood

Cisplatin may lead to problems with your blood, liver and kidneys. Your doctor will take blood samples to check for these problems.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cisplatin Sterile Concentrate

Keep this medicine out of the sight and reach of children.

Expiry

Do not use this medicine after the expiry date which is stated on the vial label and carton after 'EXP'. The expiry date refers to the last day of that month.

Storage

Do not store above 25°C. Do not refrigerate or freeze. Keep container in the outer carton in order to protect from light.

Prepared infusions should be used immediately, however, if this is not possible they can be stored for up to 14 days provided they have been prepared in a way to exclude microbial contamination. The prepared infusions should not be refrigerated.

6. Contents of the pack and other information

What Cisplatin Sterile Concentrate contains

The active substance is cisplatin. Each millilitre (ml) of solution contains 1 milligram (mg) of cisplatin.

The other ingredients are mannitol, sodium chloride, dilute hydrochloric acid and water for injections (see section 2 'Cisplatin Sterile Concentrate contains sodium').

What Cisplatin Sterile Concentrate looks like and contents of the pack

Cisplatin Sterile Concentrate is a clear, colourless to pale yellow concentrate for solution for infusion which comes in glass containers called vials.

It may be supplied in packs containing:

1 or 10 x 10 mg/10 ml vial

1 or 10 x 50 mg/50 ml vial

1 or 10 x 100 mg/100 ml vial

Not all pack sizes may be marketed

Marketing Authorisation Holder

Hospira UK Limited,
Walton Oaks,
Walton-On-The-Hill,
Dorking Road,
Tadworth,
Surrey,
KT20 7NS,
UK

Manufacturer

Pfizer Service Company BV,
Hoge Wei 10,
1930 Zaventem,
Belgium

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Cisplatin 1 mg/ml Sterile Concentrate

The following information is intended for healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities

Cisplatin may interact with metal aluminium to form a black precipitate of platinum. All aluminium-containing IV sets, needles, catheters and syringes should be avoided.

There is a total loss of cisplatin in 30 minutes at room temperature when mixed with metoclopramide and sodium metabisulfite in concentrations equivalent to those that would be found on mixing with a commercial formulation of metoclopramide.

Cisplatin and sodium bisulfite have been known to react chemically. Such antioxidants might inactivate cisplatin before administration if they are present in intravenous fluids.

Special precautions for disposal and other handling

The vials are for single use only. Discard any unused contents.

Refer to local cytotoxic handling guidelines.

Dilution: Cisplatin 1 mg/ml Sterile Concentrate should be diluted in 2 litres of 0.9% sodium chloride injection.

Following dilution in 0.9% sodium chloride injection to a final concentration of 0.15 mg/mL, chemical in-use stability has been demonstrated for up to 14 days at 25°C when stored in non-PVC infusion bags, and for 24 hours when stored at 25°C protected from light when prepared in PVC infusion bags. The diluted product should not be refrigerated. From a microbiological point of view, however, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and dilution should take place in controlled and validated aseptic conditions.

Administration: Should be administered only by or under the direct supervision of a qualified physician who is experienced in the use of cancer chemotherapeutic agents.

Preparation (Guidelines): Chemotherapeutic agents should be prepared for administration only by professionals who have been trained in the safe use of preparation.

Operations such as reconstitution dilution and transfer to syringes should be carried out only in the designated area.

The personnel carrying out these procedures should be adequately protected with clothing, gloves and eye shield.

Pregnant personnel are advised not to handle chemotherapeutic agents.

Contamination: In the event of contact with the skin or eyes, the affected area should be washed with copious amounts of water or normal saline. A bland cream may be used to treat the transient stinging of skin. Medical advice should be sought if the eyes are affected.

In the event of spillage, operators should put on gloves and mop the spilled material with a sponge kept in the area for that purpose. Rinse the area twice with water. Put all solutions and sponges into a plastic bag and seal it.

Disposal: Syringes, containers, absorbent materials, solution and any other contaminated material should be placed in a thick plastic bag or other impervious container and incinerated.