Package leaflet: Information for the user

Cisplatin 1 mg/ml Concentrate for Solution for Infusion
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 or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cisplatin 1mg/ml Concentrate for Solution for Infusion is and what it is used for
2. What you need to know before you use Cisplatin 1mg/ml Concentrate for Solution for Infusion
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1. What Cisplatin 1mg/ml Concentrate for Solution for Infusion is and what it is used for

Cisplatin 1mg/ml Concentrate for Solution for Infusion contains the active substance cisplatin which 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 cyostatics.

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).

Your doctor will be able to provide you with more information.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Cisplatin 1mg/ml Concentrate for Solution for Infusion

Do not use Cisplatin
- if you are allergic to cisplatin, similar anti-cancer medicines, other platinum containing compounds or any of the other ingredients of this medicine (listed in section 6)
- if you have very low numbers of blood cells (called ‘myelosuppression’), (your doctor will check this with a blood test)
- if you are breast feeding (see section “Pregnancy, breast-feeding and fertility”)
- if you have severe kidney disease
- if you have hearing difficulties

- if you are dehydrated
- if you need to have a vaccine for 'yellow fever'

Tell your doctor if the above applies to you before this medicine is used.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Cisplatin:
- if you have any symptoms of nerve damage (peripheral neuropathy) such as pins and needles, numbness or poor sense of touch. You will be examined regularly for these symptoms and treatment may be stopped if necessary.
- 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.

Cisplatin is very toxic and treatment is likely to cause some side effects.

Cisplatin can affect bone marrow causing changes to blood cell production in the body, tell your doctor if you have unusual bleeding or bruising. Do not take aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) or other medications without telling your doctor. Your doctor will test your blood frequently and check for signs of infection.

Cisplatin may cause hearing problems (ototoxicity) and kidney problems (nephrotoxicity). Renal function and hearing will be monitored prior to and during treatment. If you experience hearing changes, you must tell your doctor.
Tell your doctor if you intend to have a vaccine during treatment with Cisplatin, some live vaccines should be avoided as they can cause serious infections, and your response to other vaccine types (inactivated) may be reduced.

Other medicines and Cisplatin
Talk to your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicine, 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
- cisplatin may reduce the effectiveness of anticonvulsants (used to treat epilepsy), phenytoin blood levels may need to be checked
- the effectiveness of oral anticoagulants such as (coumarins/warfarin) may be affected, your doctor will monitor with blood tests
- buclizine, cyclizine and meclozone (antihistamine medicines), loxapine, phenothiazines and thioxanthenes (medicines used to treat psychiatric disorders) or trimethobenzamines (medicines used to prevent nausea and vomiting) may hide the symptoms of balance changes (such as dizziness or tinnitus)
- cisplatin may make the side effects of the anti-cancer medicine ifosfamide worse
- pyroxidine (vitamin B6) and altretamine (anti-cancer medicine) used in combination with cisplatin for the treatment of advanced ovarian cancer may reduce the time spent in recovery. Your doctor will discuss this with you

- bleomycin and etoposide (anti-cancer medicines) used in combination with cisplatin and lithium (used to treat mental illness) may reduce the levels of lithium in the blood. It is recommended to monitor the lithium values
- yellow fever vaccine must not be used at the same time as treatment with cisplatin due to the risk of death resulting from the vaccination. It is recommended to use an inactive vaccine
- antigout medicines such as allopurinol, colchicine, probenecid or sulfinpyrazone reduce the levels of uric acid in the blood. Your doctor may need to change your dose of Cisplatin.

Cisplatin with food and drink
There are no special recommendations concerning the use of this medicine with food and drink.

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 taking this medicine.

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

Cisplatin must not be used during pregnancy unless clearly indicated by your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
You must not use this medicine if you are breast-feeding and for 4 weeks after treatment, as cisplatin is excreted in the breast milk.

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 contains sodium
Cisplatin 10 mg/10 ml (1 mg/ ml) Concentrate for Solution for Infusion contains 35.4 mg of sodium (main component of cooking/table salt) in each 10ml 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) Concentrate for Solution for Infusion contains 177 mg of sodium (main component of cooking/table salt) in each 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) Concentrate for Solution for Infusion contains 354 mg of sodium (main component of cooking/table salt) in each 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 1mg/ml Concentrate for Solution for Infusion

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

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 usually given by injection into a vein (an intravenous infusion) over a period of 6 to 8 hours.
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).

Recommended Dose
Cisplatin (monotherapy):
The following dosages are recommended:
- a single dosage of 50 to 120 mg/m^2 body surface area (BSA), every 3 to 4 weeks
- 15 to 20 mg/m^2 per day over a 5-day period, every 3 to 4 weeks

Cisplatin in combination with other chemotherapeutical agents (combination chemotherapy):
- 20 mg/m^2 area (BSA) or more, once every 3 to 4 weeks.

For treatment of cervical cancer cisplatin is used in combination with radiotherapy or other chemotherapy medicines.

A typical dose is 40 mg/m^2 BSA 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 believe you have received 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.

If you forget to use Cisplatin
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor.

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)
- fainting or fitting
- hearing problems - you may experience ringing in the ears or hearing loss (ototoxicity)
- kidney and urine problems
- excessive tiredness and general feeling of being unwell, which could be symptoms of decreased levels of blood cells (myelosuppression). This would be confirmed with a blood test.

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)

- 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 characterised by spasms, reduced level of consciousness, confusion, slurred speech, sometimes blindness, memory loss, and paralysis
- 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
- neutropenia (an abnormally low count of a type of white blood cell called neutrophils)
- 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
- muscle cramping and pain
- spinal disease which may cause a sensation of electric shocks passing into your limbs
- stroke
- 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
- dizziness, light-headedness or fainting on standing up
- tingling, numbness or tremor in your hands, feet, arms or legs
- persistent headache
- hiccups
- liver enzymes increased, bilirubin increased
- difficulty breathing
- shortness of breath, chest pain particularly upon breathing in, and coughing up blood
- loss of appetite, anorexia
- feeling or being sick
- diarrhoea
- problems with your kidneys or urine
- high level of uric acid in the blood
- 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 uraemic 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 and to monitor electrolytes.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

Cyprus
Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
Tel.: + 357 22608607
Fax: + 357 22608669
Website: www.moh.gov.cy/phs

5. How to store Cisplatin Concentrate for Solution for Infusion

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'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage
Do not store above 25ºC. Do not refrigerate or freeze. Keep vial in the outer carton in order to protect from light.

Do not use this medicine if particles are present as the product may have deteriorated.

Following dilution in 0.9% Sodium Chloride Injection as recommended, chemical and physical in-use stability has been demonstrated for up to 14 days at 4°C when protected from light. 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 would normally not be longer than 24 hours at 2-8°C unless dilution has taken place in controlled and validated aseptic conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cisplatin 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 contains sodium)**.

What Cisplatin Concentrate for Solution for Infusion looks like and contents of the pack
Cisplatin is a clear, colourless to pale yellow concentrate for solution for infusion (free from visible particles) which comes in glass containers called vials.

It may be supplied in packs containing:
1 x 10 mg/10 ml vial

1 x 50 mg/50 ml vial
1 x 100 mg/100 ml vial

Not all pack sizes may be marketed

Marketing Authorisation Holder:
Ireland
Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building,
Ringsend Road,
Dublin 4,
D04 K7N3,
Ireland

Malta
Pfizer Hellas S.A
243 Messoghion Ave.
Neo Psychiko 15451
Greece

Cyprus
Pfizer Hellas A.E.
243 Messoghion Ave.
Neo Psychiko 15451
Greece

Local Representative for Cyprus:
Pfizer Hellas A.E. (Cyprus Branch)
Tel.: +357 22817690

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

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Cisplatin 1 mg/ml Concentrate for Solution for Infusion

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 must be avoided.

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

Cisplatin and sodium metabisulphite 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
Single use only. Discard any unused contents.

Refer to local cytotoxic handling guidelines.

Dilution prior to administration: An appropriate volume of Cisplatin 1 mg/ml Concentrate for Solution for Infusion should be diluted in 2 litres of sterile 0.9% sodium chloride injection. Dilution as recommended results in clear, colourless solution with no visible particles.

Following dilution in 0.9% sodium chloride injection, chemical and physical in-use stability has been demonstrated for up to 14 days at 4ºC. 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.

The dilution should be administered only intravenously by infusion over a period of 6 to 8 hours.

Although cisplatin is usually administered intravenously, the drug has also been given by intraperitoneal instillation to patients with intraperitoneal malignancies (e.g., ovarian tumours). Steep concentration gradients between intraperitoneal and plasma drug levels can be achieved by this route of administration.

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

Operations such as 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, container, absorbent materials, solution and any other contaminated material should be placed in a thick plastic bag or other impervious container and incinerated.