APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

CISACOR 10 (Infusion solution)

CISACOR 50 (Infusion solution)

For single IV use only

Cisplatin

Excipients with known effect: Each ml of solution for infusion contains 3,5 mg sodium.

Read all of this leaflet carefully before you start receiving CISACOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. WHAT CISACOR IS AND WHAT IT IS USED FOR:

Cisacor belongs to a group of medicines called cytotoxics which are used to kill cancer cells and tumors. It is used in both adults and children.

Cisacor is used in the treatment of various malignant growths.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN CISACOR

Cisacor should not be administered to you if:

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Initials:

- you are hypersensitive (allergic) to cisplatin, any other platinum containing product or any ingredient contained in **Cisacor**
- you have kidney or hearing impairment
- you have problems with your bone marrow (i.e decreased blood cells)
- you are pregnant or breast-feeding
- you have recently received a live vaccination.

WARNINGS AND PRECAUTIONS

Take special care with CISACOR:

- Your doctor should monitor your blood counts.
- Your doctor should perform nerve testings before and during Cisacor treatment.
- Inform your doctor immediately if you experience pins and needles in your hands and legs, swelling of the eye, blindness and seizures (fits).
- Your doctor should conduct blood tests to detect any kidney damage before each treatment with Cisacor.
- Your doctor should also perform hearing tests before each treatment with Cisacor.
- If you are of child bearing age, or able to conceive a child, you should use non-hormonal birth control (e.g barrier contraception) during treatment with Cisacor (see Pregnancy and Breastfeeding).
- Tell your doctor if you notice any loss of hearing or ringing in the ears.

Other medicines with Cisacor:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Aminoglycoside antibiotics, water tablets (e.g. furosemide and ethacrynic acid), blood pressure medication (e.g. hydralazine and propanolol), and an antifungal medicine called amphotericin B.

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- Antihistamines used to treat allergies, anti-nausea medicines (e.g. buclizine, cyclizine, meclizine, trimethobenzamide) and anti-psychotic medicines (such as phenothiazines and thioxanthenes) which can mask the effects on your hearing when you receive Cisacor.
- Anti-cancer medicines such as bleomycin and methotrexate.
- Medicines used to treat epilepsy e.g phenytoin.
- Medicines that cause blood dyscrasias (abnormal condition of the blood) such as adriamycin used for bone marrow suppression.
- Radiation therapy.
- Anti-gout medicines e.g. allopurinol, colchicine, probenecid or sulfinpyrazone.
- Mixtures that contain the preservative bisulphite (an acid sulphate) or metabisulphite.
- Mixtures with sodium bicarbonate, potassium chloride and/or an anti-cancer medicine called etoposide.
- Anti-cancer medicines known as fluorouracil, ifosfamide, paclitaxel.
- Lithium (used to treat depression)
- Blood thinners (e.g. warfarin)

Pregnancy and Breastfeeding:

- You should not receive **Cisacor** if you think you are pregnant or you are trying to become pregnant. **Cisacor** can affect the unborn baby.
- Males receiving **Cisacor** should use barrier contraception e,g. condoms.
- You should not receive **Cisacor** if you are breastfeeding. You should stop breastfeeding while you are being treated with **Cisacor**. Do not restart breastfeeding until your doctor tells you it is safe to do so. Ask your doctor or pharmacist for advice before taking any medicine

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

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Initials:

Driving and using machinery:

Do not drive or operate machinery until you know how Cisacor affects you.

CISACOR contains sodium

To be taken into consideration in patients on a low sodium diet.

3. HOW CISACOR WILL BE GIVEN TO YOU

Your healthcare professional will administer Cisacor.

Your doctor will advise you on how Cisacor will be administered to you.

You will not be expected to give yourself Cisacor. It will be given to you by a person who is qualified to do so.

Cisacor is given by infusion into a vein by a healthcare professional. It is given on a schedule as directed by your doctor.

The dosage of Cisacor is based on your age, blood cell count, kidney function, hearing tests and other medication you may be receiving.

Your doctor will tell you how long your treatment with Cisacor will last.

If you have the impression that the effect of Cisacor is too strong or too weak, tell your doctor or pharmacist.

If you are given more CISACOR than you should:

Since Cisacor will be given to you in a hospital setting, your dose will be carefully calculated by the doctors, so overdose is unlikely, however you can talk to your doctor or pharmacist if you have any concerns. In the event of overdosage your doctor will manage the overdosage.

4. POSSIBLE SIDE EFFECTS

Cisacor can have side-effects.

If any of the following happens, CISACOR should be stopped, tell your doctor immediately or go to the casualty department at your nearest hospital:

- dizziness or fainting,

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Initials:

- fast heartbeat,
- swelling of face and wheezing

These are all very serious side effects. If you have them, you may have had a serious reaction to CISACOR. You may need urgent medical attention or hospitilisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, difficulty breathing, low blood pressure, fast heart rate and mental confusion (these may be signs of a serious infection)
- pain, irritation, and inflammation at the injection site
- if your blood tests show changes in the number of red cells, white cells and platelets in your blood, which can cause you to feel ill or bruise easily
- feeling sick, tired or weak
- change in urine production and swelling of hands or legs, especially if it occurs two weeks after receiving Cisacor
- tingling or tremor in your hands and feet
- blood clot in the blood vessels which can result in a stroke.

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

Frequent side effects:

- low sodium levels (you may experience headache, nausea, vomiting, confusion and fatigue)
- changes to your heart rhythm
- nausea and vomiting

Less frequent side effects:

- ringing in the ears or changes in your hearing
- loss of appetite, hiccups
- sores in the mouth

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- seizures (fits)
- slurred speech
- loss of taste
- memory loss
- Lhermitte's sign (an electrical sensation that runs down the back and into the legs)
- temporary loss or changes in your eyesight
- chest pain
- hair loss
- muscle pain
- fever
- decreased sperm production in males
- slight increase in liver enzyme levels
- low magnesium levels (you may experience muscle twitching, weakness and exhaustion)
- dehydration
- gout (painful and swollen joints)

Not all side-effects reported for Cisacor are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Cisacor, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: **https://www.sahpra.org.za/Publications/Index/8**. By reporting side effects, you can help provide more information on the safety of CISACOR.

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Initials: 

5. HOW TO STORE CISACOR

Store at or below 25 °C. Do not refrigerate.

Store in unit carton until before use.

Protect from light. Any unused portion must be discarded.

After dilution with the recommended intravenous fluids, Cisacor is chemically and physically stable for 21 or 14 days at 20-25 °C at 0,01 mg/ml and 0,1 mg/ml concentration respectively. The diluted solution should be protected from light. Do not store diluted solutions in the refrigerator or freezer.

From a microbiological point of view, the diluted solution 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. Discard any unused portion.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the carton.

Do not dispose unused medicine in drains or sewerage systems (e.g. toilets). Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CISACOR contains:

- The active substance is cisplatin.
- Each ml of solution for infusion contains 1 mg cisplatin.
- The other ingredients are sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injection.

What CISACOR looks like and contents of the pack

- CISACOR is a clear, colourless to pale yellow solution in amber glass vials. When examined under suitable conditions of visibility should be practically free from particles.
- It is available as follows:

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Initials:

- **Cisacor 10:** is packaged in a 10 ml, USP type 1 amber glass vial with a grey rubber stopper/grey Westar rubber stopper silicon 1 and a 20 mm aluminium flip-off transparent white seal, which is further packed in an outer cardboard carton.
- **Cisacor 50:** is packaged in a 50 ml, USP type 1 amber glass vial with a grey rubber stopper /grey Westar rubber stopper silicon 1 and a 20 mm aluminium flip-off transparent white seal, which is further packed in an outer cardboard carton.

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park

6 Coombe Place, Rivonia,

Gauteng, South Africa

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5 February 2015

12 March 2021

REGISTRATION NUMBER

Cisacor 10: 43/26/1019

Cisacor 50: 43/26/1021

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