AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS: **S4**

ACCORD-CARBOPLATIN 10 mg/ml INJECTION

Carboplatin

Read all of this leaflet carefully before you start taking this medicine

- 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 Accord-Carboplatin is and what it is used for
2. What you need to know before you are given Accord-Carboplatin
3. How Accord-Carboplatin will be administered to you
4. Possible side effects
5. How Accord-Carboplatin is stored
6. Contents of the pack and other information

1. WHAT ACCORD-CARBOPLATIN IS AND WHAT IT IS USED FOR

- Advanced ovarian carcinoma
- Small cell carcinoma of the lung

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN ACCORD-CARBOPLATIN

YOU SHOULD NOT RECEIVE ACCORD-CARBOPLATIN:

- If you are hypersensitive to ACCORD-CARBOPLATIN or any related platinum product, or to any of the ingredients of ACCORD-CARBOPLATIN (listed in Section 6)
- If you have any kidney problems

- If you have bone marrow depression (resulting in fewer blood cells than normal) or bleeding at the site of your tumour.
- If you are pregnant or breastfeeding.
- If you have been given a yellow fever vaccine.

Warnings and precautions

Special care should be taken with ACCORD-CARBOPLATIN:

- You may experience an allergic reaction to this medicine, especially if you have taken similar medicines previously. Signs may include, itchy rash, hives, swelling, difficulty breathing.
- Tell your doctor if you also experience chest pain together with the allergic reaction.
- If you have kidney problems, as a reduced dose might be required.
- Your doctor will conduct regular tests to monitor your blood levels (for reduction of blood cells and signs of anaemia) and kidney function.
- Tell your doctor if have you previously been treated with medicines such as cisplatin, as there is a greater chance of you experiencing a reduction in blood cell production and kidney problems.
- You may experience loss of vision, especially if you are on a high dose and you have kidney problems.
- Your doctor will also monitor your liver function as this medicine may cause blockages of the veins in your liver.
- If you notice any changes in your hearing tell your doctor immediately.
- Speak to your doctor before taking any vaccines, as these may result in serious infections if taken with ACCORD-CARBOPLATIN.

Children and adolescents

The safety and efficacy of this medicine in children and adolescents has not been studied.

Other medicines and ACCORD-CARBOPLATIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

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

- some antibiotics called aminoglycosides, vancomycin or capreomycin as they may increase the risk of kidney or hearing problems
- some water tablets (diuretics), may increase the risk of kidney or hearing problems
- live or live-attenuated vaccines
- phenytoin and fosphenytoin (used to treat various types of convulsions and seizures), may increase the risk of a seizure
- cisplatin or other medicines which can reduce the number of cells in your blood may require changes to the dosage and frequency of your carboplatin treatment
- blood thinning medicines e.g. warfarin, may require an increase in frequency of blood coagulation monitoring
- other medicines which decrease the activity of the immune system (e.g. ciclosporin, tacrolimus, sirolimus)

Pregnancy and breast feeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you are given this medicine.

- ACCORD-CARBOPLATIN should not be used if you are pregnant or breastfeeding.
- If you are a woman of childbearing potential, you should use effective contraception while on ACCORD-CARBOPLATIN.

Driving and using machines

ACCORD-CARBOPLATIN may cause nausea, vomiting, changes in vision and hearing. Do not drive or operate machines if you experience any side effects that may interfere with your ability to do so.

It is not always possible to predict to what extent ACCORD-CARBOPLATIN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ACCORD-CARBOPLATIN affects you.

3. HOW ACCORD-CARBOPLATIN INJECTION WILL BE ADMINISTERED TO YOU:

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

- ACCORD-CARBOPLATIN will be given to you by intravenous infusion (into your vein), over 15 to 60 minutes.
- The dosage of ACCORD-CARBOPLATIN is based on the patient's body surface area (m^2).
- The usual dose is 360 to 400 mg/ m^2.
- If you have kidney problems, are elderly or taking any other similar medicines, your dose will be adjusted.

"If you have the impression that the effect of ACCORD-CARBOPLATIN INJECTION is too strong or too weak, talk to your doctor or pharmacist".

If you take more ACCORD-CARBOPLATIN than you should

Since a healthcare provider will administer ACCORD-CARBOPLATIN, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

If you forget to take ACCORD-CARBOPLATIN

Since a healthcare provider will administer ACCORD-CARBOPLATIN, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS:

ACCORD-CARBOPLATIN INJECTION can have side effects.

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

- If any of the following happens, stop taking ACCORD-CARBOPLATIN and tell your doctor immediately or go to the casualty department at your nearest hospital:
    - Difficulty breathing
    - Severe skin rash or itching
    - Swollen tongue or lips

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

- Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
    - abnormal bruising, bleeding, or signs of infection such as a sore throat and high temperature (may be signs of a problem with your bone marrow and blood cell count
    - decreased urination or blood in the urine (may be signs of a disease called haemolytic-uraemic syndrome)
    - nausea, vomiting, diarrhoea, irregular heartbeat, fatigue and decreased urination (may be signs of tumour lysis syndrome)
    - seizures, headache, confusion, changes in or loss of vision (may be a rare but reversible neurological condition called Reversible Posterior Leukoencephalopathy Syndrome)

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

Tell your doctor is you notice any of the following:

Frequent side effects:

- tingling or numbness in your hands and legs
- decrease in tendon reflexes
- changes in taste
- changes in vision or loss of vision
- changes in hearing
- shortness of breath, fatigue, swelling of ankles, irregular heartbeat (indicating heart problems)
- tightness of chest, difficulty breathing
- nausea, vomiting, stomach pain, diarrhoea, constipation
- loss of hair, skin rash, sore lips or mouth ulcers
- pain or discomfort in your bones, joints, muscles, or surrounding structures
- problems with your kidneys or urine
- extreme tiredness or weakness

Frequency unknown:

- respiratory infection (pneumonia) – symptoms include cough, fever, chills, difficulty breathing
- dry mouth, tiredness, headache due to dehydration, excessive loss of weight
- stroke
- high or low blood pressure
- abdominal pain, fever, mouth ulcers
- irritation or rash at injection site

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 Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of ACCORD-CARBOPLATIN.

5. HOW ACCORD-CARBOPLATIN IS STORED

Store at or below 25 ^{o}C. Protect from light.

Keep all medicines out of reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ACCORD-CARBOPLATIN contains

- The active substance is carboplatin.
- Each ml of injection contains 10 mg carboplatin.

- The other ingredient is water for injection.

What ACCORD-CARBOPLATIN looks like and contents of the pack

- ACCORD-CARBOPLATIN is a clear, colourless solution, free from visible particles.
- It is available in 5 ml, 15 ml, ~~or~~ 45 ml or 60 ml type I amber tubular glass vials.

HOLDER OF CERTIFICATE OF REGISTRATION

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