1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ASPLATA 50 mg/5 ml (injection)

ASPLATA 150 mg/15 ml (injection)

ASPLATA 450 mg/45 ml (injection)

ASPLATA 600 mg/60 ml (injection)

ASPLATA 1000 mg/100 ml (injection)

Carboplatin 10 mg/ ml

Read all of this leaflet carefully before you are given ASPLATA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ASPLATA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT ASPLATA CONTAINS

Each millilitre (ml) of injection solution contains 10 milligrams (mg) of the active ingredient, carboplatin.

The other ingredient is water for injection.

WHAT ASPLATA IS USED FOR

ASPLATA is an anti-cancer medicine in the form of solution for injection (a solution that can be given as a slow injection via a drip). It contains platinum. Carboplatin is used in the treatment of certain types of lung cancer and ovarian cancer.

BEFORE YOU RECEIVE ASPLATA (injection)

Do not receive ASPLATA (injection)

If you are:

- hypersensitive (allergic) to carboplatin or any similar medicines on previous occasions
- suffer from severe kidney disease
- suffer from hearing impairment
- Bone marrow depressed
- Pregnant, trying to become pregnant or breast-feeding your baby.

Take special care with ASPLATA (Injection)

- If you have a history of allergic reactions with platinum containing products
- To ensure the number of cells in your blood does not drop too low. Your doctor will regularly check for this
- If you have mild renal or liver disease
- If you are being given other anti-cancer medicines
- If you have been given other medicines that may affect your kidneys or hearing
- If you are older than 65 years old and experience tingling or burning of the skin

Pregnancy and breastfeeding

If you are pregnant or breastfeeding while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice before receiving ASPLATA.

It is not recommended that you become pregnant during treatment with ASPLATA. Appropriate contraceptive measure must be used during the treatment and for 4 months afterwards. It is very important to inform your doctor immediately if you become pregnant or planning to become pregnant. You must not breastfeed while you are being treated with ASPLATA. ASPLATA can harm the foetus.

Driving and using machinery

Since adverse reactions such as transient visual disturbance and transient sight loss have been reported in patients receiving ASPLATA , patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that ASPLATA does not adversely affect their ability to do so (see POSSIBLE SIDE EFFECTS).

Taking other medicines with ASPLATA (injection)

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

ASPLATA interacts with aluminium to form a black precipitate (deposit). Your healthcare professional will consider this when a decision is made regarding the syringes, needles, catheters or IV sets that will be used in the course of your treatment.

- Bone marrow depressants and radiation used together with ASPLATA may cause an increase in the bone marrow depression and gastrointestinal side effects.

- If you are taking medicine that cause the blood components to be abnormal, your doctor may adjust the dose of ASPLATA depending on blood tests he will perform.
- If you have been given cisplatin before you may experience hearing problems and tingling, pricking or numbness in your feet and hands when given ASPLATA. You may experience these effects if you are given ASPLATA with other anti-cancer medicines.
- Medicines known to cause damage to the kidneys (nephrotoxic) or to the ears (ototoxic) such as certain antibiotics (e.g. vancomycin, aminoglycosides, capreomycin) and water tablets.
- The use of killed virus vaccines together with ASPLATA may decrease your antibody response to the vaccine. Live virus vaccine must not be used when receiving ASPLATA.

HOW ASPLATA (injection) IS ADMINISTERED

The dose of ASPLATA given to you will depend on your age, your health, how well your kidneys are working and any other medicines you may be taking. ASPLATA is not normally given to children.

ASPLATA may be diluted with glucose (sugar solution) or sodium chloride (salt solution) before it is given to you. It will be given slowly, usually via a drip into a vein over 15 -60 minutes. You may be given another dose of ASPLATA after 4 weeks

ASPLATA may be given together with other anti-cancer medicines.

ASPLATA will be given to you by a healthcare professional only. He or she will have the required dose prepared for you.

While receiving ASPLATA your doctor will take regular blood tests. This is to measure the effect the medicine is having and whether further doses of ASPLATA are necessary.

If you receive more or less ASPLATA than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

POSSIBLE SIDE EFFECTS

ASPLATA can cause side effects.

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

If any of the following happens, stop ASPLATA and tell your doctor

- Signs of allergic reaction and these include difficulty in breathing; raised, coloured blotches that may be itchy; swelling and/or flushing (redness) of the face
- Fainting.

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

Tell your doctor immediately if you notice any of the following:

- abnormal heart beat (faster, slower or irregular)
- 'yellowing of the skin and eyes, also called jaundice'
- chest pains
- destruction of red blood cells. Symptoms include but are not limited to swelling (water retention), nausea/vomiting and diarrhoea,
- bleeding (haemorrhagic complications).

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- feeling faint , dizzy or about to collapse
- feeling weak and tired due to decrease in white and red blood cells
- stomach pains, diarrhoea, nausea, vomiting
- loss of hair
- unexplained bruising or bleeding
- fever
- flu like symptoms
- redness, irritation, pain or swelling at the injection site
- raised serum creatinine levels (kidney function tests).

The following side effects have been reported less frequently:

- Tingling in your hands, feet, arms and legs
- Changes in your eye sight, inability to see properly or not at all
- Ringing in your ears
- Tight chest
- Taste alteration or loss of appetite
- Constipation
- Increased bilirubin level (liver test)
- Kidney problems
- Feeling or being sick
- Complications with infections.

ASPLATA may also affect your kidney and liver function and the number of cells in your blood.

Your doctor will monitor such effects with regular blood tests.

Not all side effects reported for ASPLATA are included in this leaflet.

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

STORAGE AND DISPOSING OF ASPLATA (injection)

Store at or below 25 ℃, protected from light. Do not freeze

Keep in original packaging until required for use.

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

Your doctor or health facility will dispose of any unused solution.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ASPLATA (injection)

ASPLATA 50 mg/5 ml: 5 ml sterile solution in a 5 ml Flint (type 1) vial with a grey rubber stopper and a white flip off aluminium seal.

ASPLATA 150 mg/15 ml: 15 ml sterile solution in a 20 ml Flint (type 1) vial with a grey rubber stopper and a white flip off aluminium seal.

ASPLATA 450 mg/45 ml: 45 ml sterile solution in a 100 ml Flint (type 1) vial with a grey rubber stopper and a white flip off aluminium seal.

ASPLATA 600 mg/60 ml: sterile solution in a 100 ml Flint (type 1) vial with a grey rubber stopper and a blue flip off aluminium seal

ASPLATA 1000 mg/100 ml: sterile solution in a 100 ml Flint (type 1) vial with a grey rubber stopper and a white flip off aluminium seal.

Each vial will be packing in an outer carton.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ASPLATA (Injection)

Clear, colourless to pale yellow solution filled into flint vial with a rubber stopper and aluminium seal.

REGISTRATION NUMBER

ASPLATA 50 mg/5 ml:	-	46/26/0066
ASPLATA 150 mg/15 ml:	-	46/26/0067
ASPLATA 450 mg/45 ml:	-	46/26/0076
ASPLATA 600 mg/60 ml:	-	46/26/0068
ASPLATA 1000 mg/100 ml:	-	46/26/0069

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