1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME STRENGTH AND PHARMACEUTICAL FORM

ASPEN OXALIPLATIN 50 mg/10 ml (solution for injection)

ASPEN OXALIPLATIN 100 mg/20 ml (solution for injection)

ASPEN OXALIPLATIN 200 mg/40 ml (solution for injection)

Read this entire leaflet carefully before ASPEN OXALIPLATIN is administered to you

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

WHAT ASPEN OXALIPLATIN CONTAINS

The active substance is oxaliplatin: Each ASPEN OXALIPLATIN 50mg/10ml vial contains 10 ml of aqueous solution equivalent to 50 mg of oxaliplatin.

Each ASPEN OXALIPLATIN 100 mg/20ml vial contains 20 ml of aqueous solution equivalent to 100 mg of oxaliplatin.

Each ASPEN OXALIPLATIN 200 mg/40ml vial contains 40 ml of aqueous solution equivalent to 200 mg of oxaliplatin.

The other ingredient is water for injection.

WHAT ASPEN OXALIPLATIN IS USED FOR

ASPEN OXALIPLATIN is an antineoplastic or anticancer medicine and contains platinum.

ASPEN OXALIPLATIN in combination with other anticancer medicines called 5-fluorouracil (5-FU) and folinic acid (FA) is used for the treatment of cancer of the large bowel.

BEFORE RECEIVING ASPEN OXALIPLATIN

ASPEN OXALIPLATIN must not be administered to you if :

- you are allergic (hypersensitive) to oxaliplatin, or to other platinum-containing medicines.
- you are pregnant and/or breastfeeding.
- you have decreased blood cell production.
- you have severe kidney problems.
- you have difficulty performing delicate tasks and have tingling and numbness in the fingers and/or toes.

Take special care with ASPEN OXALIPLATIN

- If you have moderate kidney problems.
- If you have a history of allergic reactions.

ASPEN OXALIPLATIN may affect the ability to father a healthy baby. If you are a male patient, you are advised not to father a child up to 6 months after treatment and to seek advice on sperm conservation prior to treatment.

Pregnancy and breastfeeding

The safety of ASPEN OXALIPLATIN during pregnancy and whilst breastfeeding has not been established.

It is not recommended that you become pregnant during treatment with ASPEN OXALIPLATIN. Female patients should take appropriate contraceptive measures during and after termination of therapy, continuing for 4 months. It is very important to inform your doctor if you are pregnant or

planning a pregnancy before you receive any treatment. If you get pregnant during your treatment you must immediately inform your doctor.

If you are pregnant or breastfeeding your baby while receiving ASPEN OXALIPLATIN, please consult your doctor, pharmacist or other healthcare professionals for advice.

You must not breastfeed your baby while you are being treated with ASPEN OXALIPLATIN.

Driving and using machinery

Since adverse reactions such as dizziness, nausea, vomiting, and other neurological symptoms that affect walking and balance have been reported in patients receiving ASPEN OXALIPLATIN, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that ASPEN OXALIPLATIN does not adversely affect their ability to do so (see POSSIBLE SIDE EFFECTS).

Taking other medicines with ASPEN OXALIPLATIN

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

The use of ASPEN OXALIPLATIN together with the following medicines may cause undesirable effects:

- Bone marrow depressants and radiation used together with ASPEN OXALIPLATIN may cause an increase in the bone marrow depression and gastrointestinal side effects.
- The use of live virus vaccines together with ASPEN OXALIPLATIN may decrease your antibody response to the vaccine. Immunisation should be discussed with your medical practitioner before you start treatment with ASPEN OXALIPLATIN.

HOW ASPEN OXALIPLATIN IS ADMINISTERED

ASPEN OXALIPLATIN is for adult use only. You will never give yourself ASPEN OXALIPLATIN. A qualified person, like a doctor or a nurse, will administer ASPEN OXALIPLATIN.

Dosage

The dose of ASPEN OXALIPLATIN is 85 mg/m^2 injected into a vein (intravenously). The dosage may be adjusted if you have previously experienced any side effects with ASPEN OXALIPLATIN.

Frequency of administration

You should receive your dose once every 2 weeks for a period of up to 6 months.

Method and route of administration

ASPEN OXALIPLATIN will always be given to you before fluoropyrimidines.

ASPEN OXALIPLATIN will be diluted with glucose (sugar solution) before it is given to you. This will then be given slowly, usually via a drip into a vein over a 2 to 6 hour period.

If you receive more ASPEN OXALIPLATIN than you should

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

POSSIBLE SIDE EFFECTS

ASPEN OXALIPLATIN can have side effects.

Should any of the following occur, inform your doctor immediately:

Not all side effects reported for ASPEN OXALIPLATIN are included in this leaflet. Should your general health worsen while receiving ASPEN OXALIPLATIN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop receiving ASPEN OXALIPLATIN and tell your doctor immediately

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Skin rash or itching.
- Fainting.
- Yellowing of your skin and eyes (also called jaundice).

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

Tell your doctor immediately if you notice any of the following

- Chest pain, throat or chest tightness.
- Difficulty in breathing, bronchoconstriction (leading to symptoms such as coughing, wheezing and shortness of breath).
- Upper respiratory infection, group of lung diseases (affecting the tissue and space around the air sacs of your lungs).
- Pulmonary embolism (the sudden blockage of an artery in your lung).
- Pulmonary fibrosis (scarring of the lungs).
- Cancer of the blood or bone marrow (leukaemia).
- Blood in your urine or faeces.
- ASPEN OXALIPLATIN causes a temporary reduction in the number of blood cells. The reduction of red cells may cause anaemia, abnormal bleeding or bruising (due to a reduction in platelets). The reduction in white blood cells may make you prone to infections.
- Swelling or inflammation of a vein caused by a blood clot (thrombophlebitis).

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

Tell your doctor as soon as possible if you notice any of the following

- Sensation of discomfort, pain or inflammation close to or at the site of injection during the infusion.
- Altered appetite (weight loss or weight increase), nausea, vomiting, diarrhoea, inflammation of the mucous lining within the mouth (stomatitis) and that of the digestive tract (mucositis), stomach pain and constipation.
- Dehydration, partial or complete blockage (obstruction) of your bowels, heartburn, gastroesophageal reflux disease (stomach acid coming up from your stomach into the oesophagus (food pipe), hiccup, flatulence, bloody or watery diarrhoea, taste disturbances, inflammation of your pancreas (characterised by mild to severe stomach pain, nausea, fever, fatigue, irritability, headache or rapid heartbeat).
- Hand and foot disease (an illness that causes sores in or on the mouth and on the hands, feet and sometimes the buttocks and legs, which can be painful).
- Muscular weakness, joint pain, muscle pain or spasm, involuntary muscle contractions, loss of muscle coordination, balance disorders, and headache, decrease in bone marrow activity (characterised by a decrease in blood cell production), back pain.
- Flushing, nose bleeds.
- Fever, rigors (shaking movement or chills), mild or severe tiredness, body pain.
- ASPEN OXALIPLATIN can affect your nerves (peripheral neuropathy). You may feel a tingling and/or numbness in your fingers, toes, around your mouth or in your throat, which may sometimes occur in association with cramps. You may also have difficulty in performing delicate tasks, such as buttoning clothes.
- Meningeal irritation (neck stiffness).
- Jaw spasm, abnormal coordination, abnormal movement.

- Conjunctivitis, abnormal vision, double vision, drooping eyelid (ptosis), eye pain, visual disorders, secretion of tears, inflammation of the optic nerve which may cause a complete or partial loss of vision.
- Loss of your voice, hoarseness, weakness of one or both vocal folds, abnormal sensation of your tongue, speech disorder.
- Damage to your ear, deafness.
- Rhinitis (runny nose), skin rash and exfoliation, increased sweating, nail disorders, mild hair loss (temporary).
- Coughing.
- Alteration in blood tests, including those relating to abnormalities in liver function.
- Altered mental status, sleeping difficulties, loss of deep tendon (ligament) reflexes, Lhermitte's sign (an electrical sensation that runs down your back and into your limbs, dizziness.
- Painful urination, abnormal urination frequency, acute kidney failure.

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

STORING AND DISPOSING OF ASPEN OXALIPLATIN

Store at or below 30 °C.

Do not freeze. Protect from light.

Keep in original container until required for use.

For single use only.

Any unused solution should be discarded.

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

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

PRESENTATION OF ASPEN OXALIPLATIN

ASPEN OXALIPLATIN 50 mg/10 ml: 20 ml/20 mm type I siliconised clear glass vial with grey bromobutyl omniflex-coated rubber closure and grey aluminium flip-off seal.

ASPEN OXALIPLATIN 100 mg/20 ml: 20 ml/20 mm type I siliconised clear glass vial with grey bromobutyl omniflex-coated rubber closure and red aluminium flip-off seal.

ASPEN OXALIPLATIN 200 mg/40 ml: 50 ml/20 mm type I siliconised clear glass vial with grey bromobutyl omniflex-coated rubber closure and grey aluminium flip-off seal.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ASPEN OXALIPLATIN

ASPEN OXALIPLATIN 50 mg/10 ml: A sterile, clear, colourless aqueous solution free from visible particles.

ASPEN OXALIPLATIN 100 mg/20 ml: A sterile, clear, colourless aqueous solution free from visible particles.

ASPEN OXALIPLATIN 200 mg/40 ml: A sterile, clear, colourless aqueous solution free from visible particles.

REGISTRATION NUMBERS

ASPEN OXALIPLATIN 50 mg/10 ml: 45/26/0921

ASPEN OXALIPLATIN 100 mg/20 ml: 45/26/0922

ASPEN OXALIPLATIN 200 mg/40 ml: 45/26/0923

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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