Oxaliplatine

MYLAN 5 mg/mL

50mg | 100mg

1 *vial of 50 mg*
powder for solution for infusion

or

1 *vial of 100 mg*
powder for solution for infusion

IV *intravenous infusion*

Mylan

Package leaflet: information for the user

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

Benta S.A.L.
Dbayeh-Lebanon

Under license from
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1. What Oxaliplatine Mylan is and what it is used for?

The active ingredient of Oxaliplatine Mylan is oxaliplatin.
Oxaliplatine Mylan is used to treat cancer of the large bowel (treatment of stage III colon cancer after complete resection of primary tumour, metastatic cancer of colon and rectum).Oxaliplatine Mylan is used in combination with other anticancer medicines called 5 fluorouracil and folinic acid.
Oxaliplatine Mylan has to be dissolved and made into a solution before it can be injected into a vein. Oxaliplatine Mylan is an anticancer drug and contains platinum.

2. Before you use Oxaliplatine Mylan

Do not use Oxaliplatine Mylan:
- If you are allergic (hypersensitive) to oxaliplatin or any other ingredient of Oxaliplatine Mylan, like lactose monohydrate.
- If you are breast-feeding.
- If you already have a reduced number of blood cells.
- If you already have tingling and numbness in the fingers and/or toes; and have difficulty performing delicate tasks, such as buttoning clothes.
- If you have a severe kidney problem.

Take special care with Oxaliplatine Mylan:
- If you have ever suffered an allergic reaction to platinum-containing medicines such as carboplatin, cisplatin.
- If you have moderate kidney problems.
- If you have any liver problems.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
You must not use oxaliplatin during pregnancy unless clearly indicated by your doctor
You must not become pregnant during treatment with oxaliplatin and you must use an effective method of contraception.
If you get pregnant during your treatment, you must immediately inform your doctor.
You should take appropriate contraceptive measures during and after cessation of therapy continuing for 4 months for women and 6 months for men. Oxaliplatin may have an anti-fertility effect, which could be irreversible. Male patients are therefore advised not to father a child during and up to 6 months after treatment and
to seek advice on conservation of sperm prior to treatment.
You must not breast-feed while you are treated with oxaliplatin.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Oxaliplatin treatment may result in an increased risk of dizziness, nausea and vomiting, and other nervous symptoms that affect gait (difficulty walking or moving) and balance (ability to stay upright or dizziness upon standing). If this happens you should not drive or operate machinery.

3. How to use Oxaliplatine Mylan?

Oxaliplatine Mylan is intended for adults only.

Dosage
The dose of oxaliplatin is based on your body surface area. This is calculated from your height and weight.
The usual dose for adults including the elderly is 85 mg/m² of body surface area. The dose you receive will also depend on the results of your blood test and whether you have previously experienced side effects with oxaliplatin.

Method and route of administration
Oxaliplatine Mylan will be prescribed for you by a specialist in cancer treatment.
You will be treated by a healthcare professional who will have made up the required dose of oxaliplatin.
This medicine is given by slow injection into one of your veins (an intravenous infusion) over a 2 to 6 hours period. This medicine will be given to you at the same time as folinic acid and before the infusion of 5 fluorouracil.

Frequency of administration
It is determined by your doctor. For information, infusions should be repeated once every two weeks.

Duration of treatment
It is determined by your doctor.
Your treatment will last a maximum of 6 months when used after complete resection of your tumour.

If you are given more Oxaliplatine Mylan than you should be given:
As this medicine is given in a hospital, it is unlikely that you will be given too little or too much, however tell your doctor or pharmacist if you have any concerns.
In case of overdose, you may experience an increase in side effects. Your doctor may give you appropriate treatment for these side effects.
If you have any questions about your treatment, ask your doctor, nurse or your pharmacist.

4. Possible side effects

Like all medicines, Oxaliplatine Mylan can cause side effects, although not everybody gets them.

If you experience any side effect it is important that you inform your doctor before your next treatment.

Tell your doctor immediately if you notice any of the following:
• Abnormal bruising, bleeding or signs of infection such as a sore throat and high temperature • Persistent or severe diarrhoea or vomiting • Stomatitis/mucositis (sore lips or mouth ulcers) • Unexplained respiratory symptoms such as a non-productive cough, difficulty in breathing or crackles • Symptoms of angioedema (swelling of the hands or feet or ankles or face or lips or mouth or throat) which may cause difficulty in swallowing or breathing.

The very common side effects (occurs in more than 1 in 10 users) are:
• A disorder of the nerves, which can cause weakness, tingling or numbness in the fingers, toes, around the mouth or in th throat that may sometimes occur in association with cramps. This is often triggered by exposure to the cold, e.g. opening a refrigerator or holding a cold drink. You may also have difficulty in performing delicate tasks, such as buttoning clothes. Although in the majority of cases these symptoms disappear completely, there is a possibility of persistent symptoms after the end of the treatment
• Some people have experienced a tingling, shock-like sensation passing down their arms or trunk when the neck is flexed • Oxaliplatin can sometimes casue an unpleasant sensation in the throat, in particular when swallowing, and give the sensation of shortness of breath. This sensation, if it happens, usually occurs during or within hours of the infusion and may be triggered by exposure to the cold. Although unpleasant, it will not last long and goes away without the need for any treatment. Your doctor may decide to alter your treatment as a result • Signs of infection such as a sore throat and high temperature • This medicine causes temporary reduction in the number of blood cells. Reduction in the number of white blood cells, which make infections more likely; Reduction in blood platelets, which increases the risk of bleeding or bruising; Reduction in red blood cells, which can make the skin pale and cause weakness or breathlessness. Your doctor will take blood to check that you have sufficient blood cells before you start treatment and before each subsequent course • Allergic reactions - skin rash including red itchy skin, swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing) and you may feel you are going to faint, bronchospasm, sensation of chest pain, and anaphylactic shock (severe allergic reaction) • Loss or lack of appetite • Excessive levels of glucose (sugar) your blood which may cause great thirst, dry mouth or a need to urinate more often • Low blood levels of potassium which can cause abnormal heart rhythm • Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits or coma • Taste disorder • Headache • Nosebleeds • Shortness of breath • Coughing • Nausea (feeling sick), vomiting (being sick) - medication to prevent sickness is usually given to you by your doctor before treatment and may be continued after treatment • Diarrhoea - if you suffer from persistent or severe diarrhoea or vomiting contact your doctor immediately for advice • Sore mouth or lips, mouth ulcers • Stomach pain, constipation • Skin disorder • Hair loss • Back pain • Tiredness, loss of strength/weakness, body pain • Pain or redness close to or at the injection site during the infusion which can lead to necrosis (death of cells and living tissue) in case of extravasation (leakage of blood) • Fever with possible involuntarymovements of the hand or other member • Blood tests which show changes in the way the liver is working • Blood tests which show increase in lactate deshydrogenase (enzyme).

Common side effects (occurs in less than 1 in 10 users) are:
• Runny nose • Chest infection • Infection due to a reduction in white blood cells, septicaemia • Dehydration • Depression • Insomnia • Dizziness • Swelling of the nerves to your muscles • Neck stiffness, intolerance/dislike bright light and headache • Conjunctivitis, visual problems • Abnormal bleeding • Blood clot, usually in a leg, which causes pain swelling or redness • Blood clot in the lungs which cause chest pain and breathlessness • Flushing •Hiccups • Indigestion and heartburn • Lower gastrointestinal bleeding • Flaking skin, skin rash, increased sweating and nail disorder • Joint pain and bone pain • Blood in the urine • Pain on passing uring or a change in frequency of passing urine • Blood tests which show changes in the way the kidney is working • Loss of weight.

Uncommon side effects (occurs in less than 1 in 100 users) are:
• Blood tests which show an increase in acidity • Feeling anxious or nervous • Hearing problems • Impaired or blocked bowel passage • Nervous symptoms including involuntary contractions of the muscles, sensation of compression the throat or chest, or symptoms that affect gait (difficulty walking or moving) and balance (ability to stay upright or dizziness upon standing) • Symptoms which show changes in the way the cranial nerve is working (eye and sight disorders, speech and voice disorders, strong facial pain).

Rare side effects (occurs in less than 1 in 1,000 users) are:
• Reduction in blood platelet (deficiency of blood platelets with abnormal bruising and bleeding, with the body being allergic to oxaliplatin) • Abnormal reduction of red blood cells

(anaemia as a result of excessive breakdown of the blood) • Slurred speech • Visual problems such as reduction of keenness/sharpness of perception or visual field
• Inflammation of the optic nerve • Deafness (hearing impairment) • Unexplained respiratory symptoms, difficulties in breathing, scarring of the lungs which causes shortness of breath • Inflammation of the large bowel which causes abdominal pain or diarrhoea.

Very rare side effects (occurs in less than 1 in 10,000 users) are:
• Liver disease that your doctor will monitor you for • Changes in kidney function • Inflammation of the pancreas.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Oxaliplatine Mylan?

Keep out of the reach and sight of children.
No special precaution for storage for the unopened vials.
Do not use after the expiry date which is stated on the carton or vial.
When the infusion has finished, the medicine will be disposed of carefully by the doctor or nurse.

6. Further information

What Oxaliplatine Mylan contains?
The active substance is:
Oxaliplatin ..... 5 mg
For 1 ml of reconstituted solution
A vial contains 50 mg oxaliplatin for reconstitution in 10 ml of solvent.
A vial contains 100 mg oxaliplatin for reconstitution in 20 ml of solvent.
***The other ingredient is**: lactose monohydrate.*

What Oxaliplatine Mylan looks like and contents of the pack?
This medicine is in the form of a powder for solution for infusion.
One ml of reconstituted solution contains 5 mg of oxaliplatin.
Vial of 50 mg or 100 mg of powder. Pack of 1 vial.

This leaflet was last approved: 08/2013.

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

The following information is intended for medical or healthcare professionals only:

Instruction for use, handling and disposal of Oxaliplatine Mylan:
As with other potentially toxic compounds, caution should be exercised when handling and preparing oxaliplatin solutions.

1. Instructions for Handling
The handling of this cytotoxic agent by healthcare personnel requires every precaution to guarantee the protection of the handler and his surroundings.

The preparation of injectable solutions of cytotoxic agents must be carried out by trained specialist personnel with knowledge of the medicines used, in conditions that guarantee the integrity of the medicinal product, the protection of the environment and in particular the protection of the personnel handling the medicines, in accordance with the hospital policy. It requires a preparation area reserved for this purpose. It is forbidden to smoke, eat or drink in this area.
Personnel must be provided with appropriate handling materials, notably long sleeved gowns, protection masks, caps, protective goggles, sterile single-use gloves, protective covers for the work area, containers and collection bags for waste. Excreta and vomit must be handled with care.

Pregnant women must be warned to avoid handling cytotoxic agents.
Any broken container must be treated with the same precautions and considered as contaminated waste. Contaminated waste should be incinerated in suitably labelled rigid containers. See below chapter "Disposal".
If oxaliplatin powder, reconstituted solution or solution for infusion, should come into contact with skin, wash immediately and thoroughly with water
If oxaliplatin powder, reconstituted solution or solution for infusion, should come into contact with mucous membranes, wash immediately and thoroughly with water..

2. Special precautions for administration
- DO NOT use injection equipment containing aluminium.
- DO NOT administer undiluted.
- Only glucose 5 % (50 mg/ml) infusion solution is to be used as a diluent. DO NOT reconstitute or dilute for infusion with sodium chloride or chloride containing solutions.
- DO NOT mix with any other medicinal products in the same infusion bag or administer simultaneously by the same infusion line. DO NOT mix with alkaline medicinal products or solutions, in particular 5 fluorouracil (5 FU), folinic acid (FA) preparations containing trometamol as an excipient and trometamol salts of others active substances. Alkaline medicinal products or solutions will adversely affect the stability of oxaliplatin.

Instruction for use with folinic acid (FA) (as calcium folinate or disodium folinate):
Oxaliplatin 85 mg/m2 intravenous infusion in 250 to 500 ml of glucose 5 % (50 mg/ml) solution is given at the same time as folinic acid (FA) intravenous infusion in glucose 5 % (50 mg/ml) solution, over 2 to 6 hours, using a Y-line placed immediately before the site of injection. These two medicinal products should not be combined in the same infusion bag. Folinic acid (FA) must not contain trometamol as an excipient and must only be diluted using isotonic glucose 5 % (50 mg/ml) solution, never in alkaline solutions or sodium chloride solutions.

Instruction for use with 5 fluorouracil (5 FU):
Oxaliplatin should always be administred before fluoropyrimidines – i.e. 5 fluorouracil (5 FU).
After oxaliplatin administration, flush the line and then administer 5 fluorouracil (5 FU).
- USE ONLY the recommended solvents.
- Any reconstituted solution that shows evidence of precipitation should not be used and should be destroyed with due regard to legal requirements for disposal of hazardous waste.

3. Preparation of the reconstituted solution (5 mg oxaliplatin/ml)
- Water for injections or glucose 5 % (50 mg/ml) solution should be used to reconstitute the solution.
- For a vial of 50 mg: add 10 ml of solvent to obtain a concentration of 5 mg oxaliplatin/ml.
- For a vial of 100 mg: add 20 ml of solvent to obtain a concentration of 5 mg oxaliplatin/ml.
From a microbiological and chemical point of view, the reconstituted solution should be diluted immediately with glucose 5 % (50 mg/ml) solution.
Inspect visually prior to use. Only clear solutions without particles should be used.
The medicinal product is for single use only. Any unused solution should be discarded.

4. Preparation of the infusion solution
Withdraw the required amount of reconstituted solution from the vials and then dilute with 250 to 500 ml of a glucose 5 % (50 mg/ml) solution to give an oxaliplatin concentration between not less than 0.2 mg/ml and 0.7 mg/ml. Administer by intravenous infusion.

After dilution in glucose 5 % (50 mg/ml) solution, chemical and physical in-use stability has been demonstrated for 24 hours at 2 °C to 8°C.
From a microbiological point of view, the infusion preparation 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 °C to 8 °C unless dilution has been taken place in controlled and validated aseptic conditions.

Inspect visually prior to use. Only clear solutions without particles should be used.
The medicinal product is for single use only. Any unused infusion solution should be discarded (see chapter "Disposal" below).

NEVER use sodium chloride solutions for either reconstitution or dilution.
The compatibility of oxaliplatin solution for infusion has been tested with representative, PVC-based, administration sets.

5. Infusion of the solution
The administration of oxaliplatin does not require prehydration.
Oxaliplatin diluted in 250 to 500 ml of a glucose 5 % (50 mg/ml) solution to give a concentration not less than 0.2 mg/ml must be infused either by peripheral vein or central venous line over 2 to 6 hours.
When oxaliplatin is administered with 5 fluorouracil (5 FU), the oxaliplatin infusion must precede the administration of 5 fluorouracil (5 FU).

6. Disposal
Remnants of the medicinal product as well as all materials that have been used for reconstitution, for dilution and administration must be destroyed according to hospital standard procedures applicable to cytotoxic agents and with due regard to current laws related to the disposal of hazardous waste.

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