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	Customer	Accord		Black
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	Market	Ireland		
	Language	English		
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	Min. Font Size	8.5 (page 1 of 2)		
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PACKAGE LEAFLET: INFORMATION FOR THE USER
**Oxaliplatin 5mg/ml concentrate
for Solution for Infusion**

Oxaliplatin
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 doctor or your pharmacist.
- 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:

1. What Oxaliplatin Concentrate for solution for infusion is and what it is used for
2. Before you use Oxaliplatin Concentrate for solution for infusion
3. How to use Oxaliplatin Concentrate for solution for infusion
4. Possible side effects
5. How to store Oxaliplatin Concentrate for solution for infusion
6. Further information

1. What Oxaliplatin Concentrate for solution for infusion is and what it is used for

The name of your medicine is 'Oxaliplatin 5mg/ml concentrate for Solution for Infusion' but in the rest of the leaflet it will be called 'Oxaliplatin concentrate for solution for infusion'.
The active ingredient of oxaliplatin concentrate for solution for infusion is oxaliplatin.
Oxaliplatin concentrate for solution for infusion 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). Oxaliplatin concentrate for solution for infusion is used in combination with other anticancer medicines called 5 fluorouracil and folinic acid.
Oxaliplatin concentrate for solution for infusion has to be dissolved and made into a solution before it can be injected into a vein. Oxaliplatin concentrate for solution for infusion is an antineoplastic or anticancer drug and contains platinum.

2. Before you use Oxaliplatin Concentrate for solution for infusion

You should not be given Oxaliplatin Concentrate for solution for infusion

- if you are allergic (hypersensitive) to oxaliplatin or any of the other ingredients of the Oxaliplatin concentrate for solution for infusion including lactose monohydrate,
- if you already have a reduced number of blood cells,
- if you breast feeding,
- 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 severe kidney problems.

Take special care with Oxaliplatin concentrate for solution for infusion

- if you have ever suffered an allergic reaction to platinum- contain-

ing medicines such as carboplatin, cisplatin

- if you have moderate kidney problems
- if you have any liver problems
- If you are pregnant or planning a pregnancy it is very important that you discuss this with your doctor **before** you receive any treatment. 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.

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:
Pregnancy

You must not be treated with oxaliplatin unless clearly indicated by your doctor. It is not recommended that you become pregnant during treatment with oxaliplatin and 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.

Breast-feeding
You must not breast-feed while you are treated with oxaliplatin. Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines:
Oxaliplatin treatment may result in an increased risk of dizziness, nausea and vomiting, and other neurological symptoms that affect walking and balance. If this happens you should not drive or operate machinery. If you have vision problems while taking Oxaliplatin concentrate for solution for infusion, do not drive, operate heavy machines, or engage in dangerous activities.

3. How to use Oxaliplatin Concentrate for solution for infusion

Oxaliplatin concentrate for solution for infusion is intended only for adults.

Dosage
The dose of Oxaliplatin concentrate for solution for infusion 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 results of blood tests and whether you have previously experienced side effects with Oxaliplatin concentrate for solution for infusion.

Method and route of administration

- Oxaliplatin concentrate for solution for infusion 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 concentrate for solution for infusion.
- Oxaliplatin concentrate for solution for infusion is given by slow injection into one of your veins (an intravenous infusion) over a 2 to 6 hour period.
- Oxaliplatin concentrate for solution for infusion will be given to you at the same time as folinic acid and before the infusion of 5 fluorouracil.

Frequency of administration

tubular glass vial with 20 mm chlorobutyl rubber stopper and 20 mm aluminium flips off lavender seal.

Shelf life and storage:
2 years

After dilution of the solution in 5% glucose solution, chemical and physical in-use stability has been demonstrated for up to 48 hours at +2°C to +8°C and for 24 hours at +25°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 taken place in controlled and validated aseptic conditions.

Keep the vial in the outer carton in order to protect from light. Do not freeze.

Inspect visually prior to use. Only clear solutions without particles should be used.

The medicinal product is for single use only. Any unused concentrate should be discarded.

3. RECOMMENDATIONS FOR THE SAFE HANDLING

As with other potentially toxic compounds, caution should be exercised when handling and preparing oxaliplatin solutions.

Instructions for Handling

You should usually receive your infusion once every 2 weeks.

Duration of treatment
The duration of the treatment will be determined by your doctor. Your treatment will last a maximum of 6 months when used after complete resection of your tumour.

If you use more Oxaliplatin concentrate for solution for infusion than you should

As this medicine is administered by a healthcare professional it is highly unlikely that you will be given too much or too little. In case of overdose, you may experience increased 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 pharmacist.

4. Possible side effects

Like all medicines, Oxaliplatin concentrate for solution for infusion 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.

You will find described below the side effects that you could experience.

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,
- Presence of blood or dark brown coffee-coloured granules in your vomit,
- Stomatitis/mucositis (sore lips or mouth ulcers),
- Unexplained respiratory symptoms such as a dry cough, difficulties in breathing or crackles
- A group of symptoms such as headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss (symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder).

Other known side effects of Oxaliplatin concentrate for solution for infusion are:

Very common (Side effects that occur in at least 1 patient out of 10):
• Oxaliplatin concentrate for solution for infusion can affect the nerves (peripheral neuropathy). You may feel a tingling and/or numbness in the fingers, toes, around the mouth or in the throat, which may sometimes occur in association with cramps.

These effects are often triggered by exposure to 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 resolve themselves completely, there is a possibility of persistent symptoms of peripheral sensory neuropathy after the end of the treatment.

Some people have experienced a tingling, shock-like sensation passing down the arms or trunk when the neck is flexed.

- Oxaliplatin concentrate for solution for infusion can sometimes cause 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.

The following information is intended for medical or healthcare professionals only

PREPARATION GUIDE FOR USE WITH OXALIPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION

It is important that you read the entire contents of this procedure prior to the preparation of OXALIPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION

1. FORMULATION

Oxaliplatin concentrate for solution for infusion is a clear colourless solution containing 5 mg/ml oxaliplatin in lactose monohydrate.

2. PRESENTATION

Oxaliplatin concentrate for solution for infusion is supplied as single-dose vials. 1 vial per carton.

For 10 ml,
Concentrate for solution for infusion is filled in 10 ml type 1 clear tubular glass vial with 20 mm chlorobutyl rubber stopper and 20 mm aluminium flip off lavender seal.

For 20 ml,
Concentrate for solution for infusion is filled in 20 ml type 1 clear molded glass vial with 20 mm chlorobutyl rubber stopper and 20 mm aluminium flips off lavender seal.

For 40 ml,
Concentrate for solution for infusion is filled in 50 ml type 1 clear

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 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.

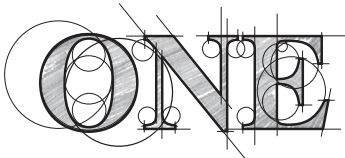

Personnel must be provided with appropriate handling materials, notably long sleeved gowns, protection masks, caps, protective goggles, sterile single-use gloves, protective covers for the work area, containers and collection bags for waste.

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 concentrate for solution for infusion, should come into contact with skin, wash immediately and thoroughly with water.

If oxaliplatin concentrate for solution for infusion, should come into contact with mucous membranes, wash immediately and

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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.

- Oxaliplatin concentrate for solution for infusion may cause diarrhea, mild nausea (feeling sick) and vomiting (being sick); however medication to prevent the sickness is usually given to you by your doctor before treatment and may be continued after treatment.
- Oxaliplatin concentrate for solution for infusion causes temporary reduction in the number of blood cells. The reduction of red cells may cause anemia (a reduction of red cells), abnormal bleeding or bruising (due to a reduction in platelets). The reduction in white blood cells may make you prone to infections. Your doctor will take blood to check that you have sufficient blood cells before you start treatment and before each subsequent course.
- Hypokalaemia (Condition of below normal levels of potassium in the blood serum)
- Natraemia (Excessive amounts of sodium in the blood)
- Fatigue (physical and/or mental exhaustion) and Asthenia (Loss or lack of bodily strength; weakness).

Your doctor will take blood to check that you have sufficient blood cells before you start treatment and before each subsequent course.

- Sensation of discomfort close to or at the injection site during the infusion,
- Fever, rigors (tremors), mild or severe tiredness, body pain,
- Weight changes, loss or lack of appetite, taste disorders, constipation,
- Headache, back pain,
- Swelling of the nerves to your muscles, neck stiffness, abnormal tongue sensation possibly altering speech, stomatitis / mucositis (sore lips or mouth ulcers),
- Stomach pain,
- Abnormal bleeding including nose bleeds,
- Coughing, difficulty in breathing,
- Allergic reactions, skin rash which may be red and itchy, mild hair loss (alopecia),
- Alteration in blood tests including those relating to abnormalities in liver function.

Common (Side effects that occur in more than 1 patient out of 100 but less than 1 patient out of 10):

- Infection due to a reduction in white blood cells
- Indigestion and heart burn, hiccups, flushing, dizziness,
- Increased sweating and nail disorders, flaking skin,
- Chest pain,
- Lung disorders and runny nose,
- Joint pain and bone pain,
- Pain on passing urine and changes in kidney function, changes of frequency of urination, dehydration,
- Blood in the urine/stools, swelling of the veins, clots in the lung,
- High blood pressure
- Depression and insomnia,
- Conjunctivitis and visual problems,
- Hyperhidrosis (A disorder marked by excessive sweating)

Uncommon (Side effects that occur in more than 1 patient out of 1,000 but less than 1 patient out of 100):

- Blockage or swelling of the bowel,
- Nervousness.

Rare (Side effects that occur in more than 1 patient out of 10,000 but less than 1 patient out of 1,000):

- Loss of hearing,
- Scarring and thickening in the lungs with difficulties in breathing, sometimes fatal (interstitial lung disease),
- Reversible short-term loss of vision.

Very rare (Side effects that occur in less than 1 patient out of 10,000):

- Presence of blood or dark brown coffee-coloured granules in your vomit.

Frequency unknown (cannot be assessed)

- Convulsion.

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 Oxaliplatin Concentrate for solution for infusion

Keep out of the reach and sight of children.

Do not use Oxaliplatin concentrate for solution for infusion after expiry date (EXP) the last day of the month, which is stated on the pack.

Prior to mixing keep the vial in the outer carton in order to protect from light. Do not freeze.

Chemical and physical in-use stability has been demonstrated for 48 hours at 2°C to 8°C and for 24 hours at +25°C. From a microbiological point of view, this 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 taken place in controlled and validated aseptic conditions.

Do not use Oxaliplatin concentrate for solution for infusion if you notice that the solution is not clear and free of particles.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. Oxaliplatin concentrate for solution for infusion should not come into contact with the eyes or skin. If there is any accidental spillage, tell the doctor or nurse immediately.

When the infusion has finished, Oxaliplatin concentrate for solution for infusion will be disposed of carefully by the doctor or nurse.

6. Further information

What Oxaliplatin Concentrate for solution for infusion contains: Oxaliplatin concentrate for solution for infusion contains the active ingredient oxaliplatin.

1 ml concentrate for solution for infusion contains 5 mg oxaliplatin
10 ml of concentrate for solution for infusion contains 50 mg of oxaliplatin.
20 ml of concentrate for solution for infusion contains 100 mg of oxaliplatin.
40 ml of concentrate for solution for infusion contains 200 mg of oxaliplatin.
The other ingredients are lactose monohydrate and water for injections.

What Oxaliplatin Concentrate for solution for infusion looks like and contents of the pack:

Oxaliplatin concentrate for solution for infusion is a clear colourless solution free from visible particles.
Each glass vial is packed in individual carton.
Not all pack size may be marketed.

Marketing Authorisation Holder and manufacturer:

Accord Healthcare Limited,
Sage House, 319 Pinner Road,
North Harrow HA1 4HF, UK

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
United Kingdom	Oxaliplatin 5 mg/ml Concentrate for Solution for Infusion Oxaliplatin Accord 5 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Austria	Oxaliplatin Accord 5 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Oxaliplatin Accord Healthcare 5 mg/ml concentré pour solution de perfusion/ concentraat voor oplossing voor infusie / Konzentrat zur Herstellung einer Infusionslösung
Bulgaria	Оксалиплатин Акорд 5 mg/ml концентрат за инфузионен разтвор
Czech Republic	Oxaliplatin Accord 5 mg/ml Koncentrát pro Přípravu Infuzního Roztoku
Germany	Oxaliplatin Accord 5 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Denmark	Oxaliplatin Accord 5 mg/ml koncentrat til infusionsvæske, opløsning.
Estonia	Oxaliplatin Accord 5 mg/ml infusioonilahuse kontsentraat
Spain	Oxaliplatino Accord 5 mg/ml Concentrado para Solución para Perfusión EFG
Finland	Oxaliplatin Accord 5 mg/ml Infuusiokonsentraatti, Liuosta Varten/ koncentrat till infusionsvätska, lösning
France	Oxaliplatin Accord 5 mg/ml concentré pour solution de perfusion
Hungary	Oxaliplatin Accord 5 mg/ml koncentrátum oldatos infúzióhoz
Ireland	Oxaliplatin 5 mg/ml Concentrate for Solution for Infusion
Italy	Oxaliplatino Accord Healthcare 5 mg/ml concentrato per soluzione per infusione
Latvia	Oxaliplatin Accord 5 mg/ml koncentrāts infūzijai
Lithuania	šķiduma pagatavošanai Oxaliplatin Accord 5 mg/ml koncentratas infuziniam tirpalui
Malta	Oxaliplatin 5 mg/ml Concentrate for Solution for Infusion
The Netherlands	Oxaliplatin Accord 5 mg/ml concentraat voor oplossing voor infusie
Poland	Oxaliplatinum Accord, 5 mg/ml, koncentrat do sporządzania roztworu do infuzji
Portugal	Oxaliplatina Accord
Romania	Oxaliplatin Accord 5 mg/ml concentrat pentru solutie perfuzabila
Sweden	Oxaliplatin Accord 5 mg/ml koncentrat till infusionsvätska, lösning

The leaflet was last approved in 06/2012.

thoroughly with water.

4. PREPARATION FOR THE INTRAVENOUS ADMINISTRATION Special precautions for administration

- DO NOT use injection equipment containing aluminium.
- DO NOT administer undiluted.
- Only 5% glucose solution is to be used as a diluent. DO NOT 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 drugs or solutions, in particular 5-fluorouracil, folic acid preparations containing trometamol as an excipient and trometamol salts of others drugs. Alkaline drugs or solutions will adversely affect the stability of oxaliplatin.

Instruction for use with folic acid (as calcium folinate or disodium folinate)

Oxaliplatin 85mg/m² IV infusion in 250 to 500 ml of 5% glucose solution is given at the same time as folic acid intravenous infusion in 5% glucose solution, over 2 to 6 hours, using a Y-line placed immediately before the site of infusion.

These two medicinal products should not be combined in the same infusion bag. Folic acid must not contain trometamol as an excipient and must only be diluted using isotonic 5% glucose solution, never in alkaline solutions or sodium chloride or chloride containing solutions.

Instruction for use with 5 fluorouracil

Oxaliplatin should always be administered before fluoropyrimidines – i.e. 5-fluorouracil.

After oxaliplatin administration, flush the line and then administer 5-fluorouracil.

For additional information on drugs combined with oxaliplatin, see the corresponding manufacturer's summary of product characteristics.

- USE ONLY the recommended solvents (see below).

4.1 Preparation of the infusion solution

Withdraw the required amount of concentrate from the vial(s) and then dilute with 250 ml to 500 ml of a 5% glucose solution to give an oxaliplatin concentration between 0.2 mg/ml and 2 mg/ml; concentration range for which the physico-chemical stability of oxaliplatin has been demonstrated.

Administer by Intravenous infusion.

After dilution in 5% glucose, chemical and physical in-use stability has been demonstrated for 48 hours at +2°C to +8°C and for 24 hours at +25°C.

From a microbiological point of view, this 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 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 concentrate should be discarded.

NEVER use sodium chloride or chloride containing solutions for dilution.

The compatibility of Oxaliplatin solution for infusion has been tested with representative, PVC-based, administration sets.

The administration of oxaliplatin does not require rehydration.

4.2 Infusion of the solution

The administration of oxaliplatin does not require rehydration. Oxaliplatin diluted in 250 to 500 ml of a 5% glucose 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, the oxaliplatin infusion must precede the administration of 5-fluorouracil.

4.3 Disposal

Remnants of the medicinal product as well as all materials that have been used for dilution and administration must be destroyed according to hospital standard procedures applicable to cytotoxic agents and in accordance with local requirements related to the disposal of hazardous waste.

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