

Oxaliplatin medac® 5mg/ml
Powder for solution for infusion.
Oxaliplatin

1. What Oxaliplatin 5mg/ml is what is it used for?

Oxaliplatin medac is an anticancer and contains platinum. Oxaliplatin is used to treat cancer of large bowel (treatment of stage III colon cancer after complete resection of primary tumor, metastatic cancer of colon or rectum).

It is used in combination with other anticancer medicines called 5FU and Folinic acid.

2. Before you are given Oxaliplatin medac 5mg/ml:

Oxaliplatin medac should not be used if you:

- Are hypersensitive (allergic) to Oxaliplatin or any other ingredient of Oxaliplatin medac.
- Are breast feeding.
- Already have a reduced number of blood cells.
- Already have tingling and numbness in the fingers &/or toes, and have difficulty performing delicate tasks.
- Have severe kidney problems.

Special care should be taken with Oxaliplatin if you:

- Have ever suffered an allergic reaction to platinum containing medicines such as carboplatin, cisplatin.
- Experience persistent or severe diarrhea, nausea or vomiting.
- Experience sore lips or mouth ulcers.
- Abnormal bruising, bleeding or signs of infection such as sore throat or fever. As Oxaliplatin can cause a reduction in number of blood cells, your doctor will check your blood frequently.
- Experience unexplained respiratory symptoms such as cough or difficulty in breathing.
- Notice a sensation of discomfort close to or at the injection site.

Pregnancy and Breast Feeding:

Ask your doctor for advice before taking any medicine.

Pregnancy

You must not become pregnant during treatment with Oxaliplatin and must use an effective method of contraception. If pregnancy occurs during treatment, inform your doctor immediately. Appropriate contraceptive measures should be taken during and after cessation of therapy, during 4 months for women and 6 months for men. Male patients are advised on conservation of sperm prior to treatment as it causes irreversible antifertility effect.

Breast-Feeding

You must not breastfeed while on treatment with Oxaliplatin.

3. How Oxaliplatin Disodium is administered to you?

Method and routes of administration

Only to be given to adults. Oxaliplatin medac is given by injection into the vein over a 2-6 hour period. The injection is made by mixing the powder with water for injection or 5% glucose. This solution is then diluted further in 5% glucose.

Dosage

The usual dose is 85mg/m² of body surface area once every 2 weeks before the infusion of the other anticancer medicines.

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

4. Possible Side Effects

Like all medicines, Oxaliplatin medac can cause side effects although not everybody gets them.

Inform your doctor, if you experience any of the following:

- Persistent or severe diarrhea or vomiting
- Sore lips or mouth ulcers
- Swelling of face, lips, mouth or throat
- Unexplained respiratory symptoms
- Difficulty in swallowing
- Numbness or tingling in fingers or toes
- Extreme tiredness
- Abnormal bruising or bleeding
- Signs of infection; sore throat or fever
- Sensation of discomfort at injection site

Very common: more than 1 in 10 patients

- Nerve disorder causing weakness, tingling or numbness in fingers, mouth or throat
- Unpleasant sensation
- Taste disorder
- Headache
- Fever, sore throat
- Reduction in blood cells WBC's (infections) & platelets (bruising & bleeding)
- Allergic reactions
- Nausea & vomiting
- Skin disorders
- Hair loss

Common: less than 1 in 10 patients

- Dehydration
- Depression
- Difficulty sleeping
- Dizziness
- Neck stiffness
- Conjunctivitis
- Weight loss

Uncommon: less than 1 in 100 patients

- Nervousness
- Hearing problems
- Constipation
- Disturbance in acid base balance

Rare: less than 1 in 1,000 patients

- Slurred speech
- Vision impairment
- Deafness
- Bowel inflammation (abdominal pain)

Very Rare: less than 1 in 10,000 patients

- Inflammation of the pancreas
- Liver disease
- Oxaliplatin should not come in contact with the skin or eyes. In case of spillage, inform the doctor

5. Storing Oxaliplatin medac

This medicinal product does not require any special storage conditions.

The reconstituted concentrate solution should be diluted immediately.

After dilution of reconstituted solution in glucose 5% solution, chemical and physical in use stability has been demonstrated for 24 hours at 2 – 8 deg C.

From a microbiological point of view, the solution should be infused immediately.

6. Further information

The active substance is Oxaliplatin

50mg vial: Each contains 50mg Oxaliplatin for reconstitution in 10ml of solvent

100mg vial: Each vial contains 100mg Oxaliplatin for reconstitution in 20ml of solvent.

One ml of the reconstituted concentrate solution contains 5mg Oxaliplatin.

The other ingredient is lactose monohydrate.

Marketing authorization holder & manufacturer:

Medac, Germany

Imported & Marketed by:

