

XALOX™

XALOX (oxaliplatin 50 mg powder for injection vial)

XALOX (oxaliplatin 100 mg powder for injection vial)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about XALOX powder for injection. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of using XALOX against the benefits it is expected to have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet as you may want to read it again.

What XALOX is used for

XALOX is used to treat cancer of the large intestine and the rectum (colorectal cancer). It is used with two other anti-cancer drugs, fluorouracil (FU) and folinic acid.

XALOX contains the active ingredient, oxaliplatin. Cancer cells have changed from normal cells so that they grow in an uncontrolled way. Oxaliplatin works by interfering with cancer cell growth. Because of the similarities between cancer cells and normal cells, anti cancer drugs often have unwanted effects on the body. Your doctors have decided to treat you with XALOX because they believe that the benefit of XALOX treatment will be greater than the unwanted effects. Many of the side effects from anti cancer drugs are predictable and can be prevented and lessened.

Your doctor and other staff will take all of the precautions needed to reduce the unwanted effects of treatment.

XALOX is available only with a doctor's prescription.

Before you are given XALOX

When you must not receive it

You should not be given XALOX if you are:

- allergic to the active ingredient, oxaliplatin. If you have had an allergic reaction to oxaliplatin before, you should not receive it again.
- allergic to any of the other medicines being given to you with XALOX.
- pregnant or breastfeeding. Oxaliplatin may cause birth defects if you are being treated with it at the time of conception or if it is given to women who are already pregnant. Adequate contraception is required during treatment with oxaliplatin. You should discuss this with your doctor. Nursing mothers are advised not to breastfeed while receiving oxaliplatin, as the effect of breast milk from such patients is unknown.
- have severe kidney disease.
- have nerve damage (peripheral sensory nerve damage).

What you should tell your doctor

You must tell your doctor if:

- You have had a reaction to any other platinum compound.
- You have severe kidney disease.
- You have nerve damage (neuropathy).

- You have any other medical condition that he or she is not aware of.
- You are taking any other medicines, including medicines that you have bought without a prescription from a pharmacy, supermarket or health food shop. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.
- You are pregnant or breastfeeding.

How XALOX is given

XALOX will be given to you as an infusion into one of your veins (this is called an intravenous infusion). The infusion will be given over 2 - 6 hours. The dose of XALOX is calculated by your doctor. Each course of treatment is called a cycle; your doctor will tell you how many cycles you will receive. XALOX will be used with fluorouracil (FU) and folinic acid.

XALOX is not recommended in children.

While you are being given XALOX

Things you must do

- Avoid cold foods and drinks.
- Cover skin prior to exposure to cold during or within 48 hours following being given oxaliplatin, since neurological effects may be brought on or worsened by exposure to cold.
- Contact your doctor immediately if you develop fever, particularly in association with persistent diarrhoea or evidence of infection since this may indicate low blood count.
- Contact your doctor if persistent vomiting, diarrhoea, signs of dehydration, cough or breathing difficulties or signs of allergic reaction occur.
- Visual disturbance is a rare side effect of oxaliplatin. Contact your doctor if this happens to you, and do not drive or use machinery until your vision is clear.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while XALOX is being given to you. You should also tell your doctor if you do not feel well between courses of XALOX.

All medicines can have side effects. It is important to understand the side effects that XALOX may cause, even though you may not experience them. As well as the predictable side effects of XALOX, there are other effects that occur much more rarely. If you have any side effects or notice anything unusual it is important to inform your doctor before your next treatment. Your doctor will decide whether such effects are because of your treatment, and what action needs to be taken.

This section explains the side effects of XALOX, and some of the checks made before each treatment to prevent excessive side effects.

- **Physical Condition:** Before each treatment with XALOX you will be examined for any condition that may be affected by chemotherapy (for example, infection, or loss of feeling). This will include those conditions caused by previous treatment, those caused by your disease, and those caused by other things.
- **Loss of Feeling:** XALOX can affect nerves in the hands and feet. This is common soon after treatment, and can appear as tingling or numbness in the fingers or toes, and may be made worse by cold temperatures or by contact with cold water or other cold objects. These symptoms often go away between treatments, but may last longer and get worse with repeated treatment. In some patients the limbs may become weak or painful. However, in most patients these symptoms improve after treatment is stopped. Tell your doctor if any of these things happen. Your doctor will examine you before treatment to see if you are affected.
- **Nausea and Vomiting:** Severe nausea and vomiting is uncommon with XALOX. Mild nausea and vomiting is more common. Medication to prevent the sickness caused by XALOX will be given before treatment, and may sometimes be continued after treatment.
- **Diarrhoea:** Severe diarrhoea may occur during treatment with XALOX. **If you suffer from persistent or severe diarrhoea or vomiting, contact your doctor urgently for treatment advice.**
- **Low Blood Counts:** XALOX can affect the body's ability to make blood cells. If your blood count is too low, your treatment may be postponed, or the dose reduced. **Tell your doctor if you notice any bruising or abnormal bleeding, or have an infection. These may be signs of a low blood count.**
- **Difficulty Swallowing:** Some patients may experience a sudden, temporary feeling of difficulty with swallowing or breathing. This sensation, if it occurs, usually happens during the injection or within hours after the infusion. It may be triggered by swallowing a cold drink. Although unpleasant, this feeling does not last long, and goes away by itself.

Tell your doctor if this happens to you.

Other known side effects of XALOX include:

- mucositis (sore lips or mouth ulcers)
- constipation
- anorexia
- conjunctivitis
- cough
- hiccup
- headache confusion
- seizures or fits
- abdominal pain
- mild hair loss (alopecia)
- fever
- inflammation around the injection site
- tiredness
- skin rash
- allergic reactions
- infection

- altered taste
- abnormal tongue sensation
- nose bleeds
- feeling of chest pressure
- voice disturbance (rare)
- loss of hearing (rare)
- visual disturbances (rare)
- lung disorders (rare).

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

If you receive too much (overdose)

Your doctor will decide what dose of XALOX you need, and this will be given under close supervision, usually in a hospital setting. The risk of an overdosage in these circumstances is low. In the event of an overdose occurring, your doctor will decide on the treatment necessary.

Storage

If you need to store XALOX before you take it with you to hospital, make sure it is stored in a cool dry place where the temperature does not exceed 25°C. Protect from light.

Do not use it after the expiry date printed on the vial.

This is not all the information that is available on XALOX. If you have any more questions or are not sure about anything ask your doctor or pharmacist.

Product description

XALOX Powder for injection contains 50 mg or 100 mg oxaliplatin and looks like a compact mass or white or almost white fragments with porous appearance.

XALOX has to be diluted with water for injections before use. It also contains lactose.

Sponsor

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