

PATIENT INFORMATION: OBINUTUZUMAB

*Renal Vasculitis Service
Royal Infirmary of Edinburgh*

Benefits of obinutuzumab

Your doctor has recommended that you are treated with obinutuzumab (for which the brand name is Gazyvaro). This medicine is designed to target your immune system. If your immune system is over-active and causing disease then obinutuzumab can help by dampening this down. Obinutuzumab can be used to treat vasculitis, systemic lupus erythematosus (SLE), and some blood cancers. Obinutuzumab targets the immune system in a similar way to a commonly used medication called rituximab, although it works in slightly different way.

How it is given

Obinutuzumab can be given as a single dose or as two doses about two weeks apart. It is given as a drip treatment into a vein. The dose is usually repeated at intervals of 6 to 12 months.

Risks of obinutuzumab

Certain people should not be treated with obinutuzumab, unless in exceptional circumstances. This includes women who are pregnant or breastfeeding because obinutuzumab may harm the baby. Please let your kidney or vasculitis doctor know if you think you might be pregnant. We advise that all women of childbearing age should use highly-effective contraception (such as the Mirena coil, implant or sterilisation) for 18 months after treatment with obinutuzumab.

Before you start this medication, we will talk to you about the possible side effects. We have included the most important risks in this information sheet.

Talk to your doctor or nurse before you are given obinutuzumab if:

- you have an infection, or have had an infection in the past which lasted a long time or keeps coming back
- you have ever taken, or been given, medicines which affect your immune system (such as chemotherapy or immunosuppressants)
- you are taking medicines for high blood pressure or medicines used to thin your blood – your doctor might need to alter how you take these
- you have ever had heart problems
- you have ever had brain problems (such as memory problems, difficulty moving or feeling sensations in your body, eyesight problems)
- you have ever had breathing problems or lung problems
- you have ever had “hepatitis B” - a type of liver disease
- you are due to have a vaccine or you know you may need to have one in the near future.

Side effects of obinutuzumab fall into two groups: infusion-related side effects that occur during the drip treatment itself or within a few hours afterwards – and late side effects, which may occur after weeks, months or years.

1. Infusion-related ‘allergic-type’ side effects

You will be given an antihistamine, paracetamol and steroid treatment immediately prior to receiving obinutuzumab, in order to minimise the chance of an ‘allergic-type’ reaction. If you have a reaction it can usually be treated by slowing or stopping the drip until you feel better, at which point the drip can usually be re-started. You will be monitored closely during your treatment, but it is very important to tell your nurse or doctor if you feel unwell or have any of the following:

- flu-like symptoms, such as headache, feeling flushed, fever, chills, or dizziness
- nausea or sickness
- red, warm and itchy bumps on the skin (like nettle rash)
- swollen lips, tongue or throat; wheezing, a cough or breathlessness
- pain in your back or tummy (including diarrhoea)
- a tight chest or chest pain.

Sometimes an infusion-related reaction can happen a few hours after treatment. If you develop these symptoms or feel unwell after you get home, contact ward 206 straight away for advice (0131 242 2061).

2. Late side effects

Infection. Obinutuzumab suppresses the body’s immune system. This means that you are more vulnerable to infections and this is likely to be the case for around a year after treatment with obinutuzumab. We will prescribe you a daily antibiotic to reduce this risk. If you are worried that you might have an infection at any time in the year after receiving obinutuzumab, then please seek medical advice straight away.

You should avoid any ‘live’ vaccines (such as the shingles vaccine) as these may be dangerous. Before receiving any vaccination, it would be sensible to discuss this first with your kidney or vasculitis doctor. However, other types of vaccines are safe. You should ensure that you are up to date with the influenza (‘flu’) and pneumococcal (‘pneumonia’) vaccinations. Ideally, these would be given at least one month prior to receiving obinutuzumab because otherwise obinutuzumab is likely to make the vaccines less effective.

Sometimes obinutuzumab may have an effect on your antibody levels or blood counts that would require extra blood tests or extra treatments.

Reactivation of previous hepatitis B infection. If you have previously been exposed to the hepatitis B virus then obinutuzumab may cause this to reactivate.

Viral infections of the brain. A very small number of patients who have been treated with obinutuzumab have developed a serious viral infection of the brain (called ‘Progressive Multifocal Leukoencephalopathy’). For patients who don’t have blood cancer, the risk is thought to be very low. The infection causes damage to the brain and may lead to disability or death. Tell your doctor or nurse straight away if you have memory loss, trouble speaking, difficulty walking or problems with your eyesight.

Risk of cancer. Increased rates of cancer have not been reported in patients who have been treated with obinutuzumab, nor with the similar medication rituximab. However, any treatment used to suppress the immune system might contribute to a small increased risk of cancer in later life.

I acknowledge that I have received the above information about obinutuzumab.

Name:

Signature:

Date:

Name of Doctor:

Signature of Doctor:

Date:
