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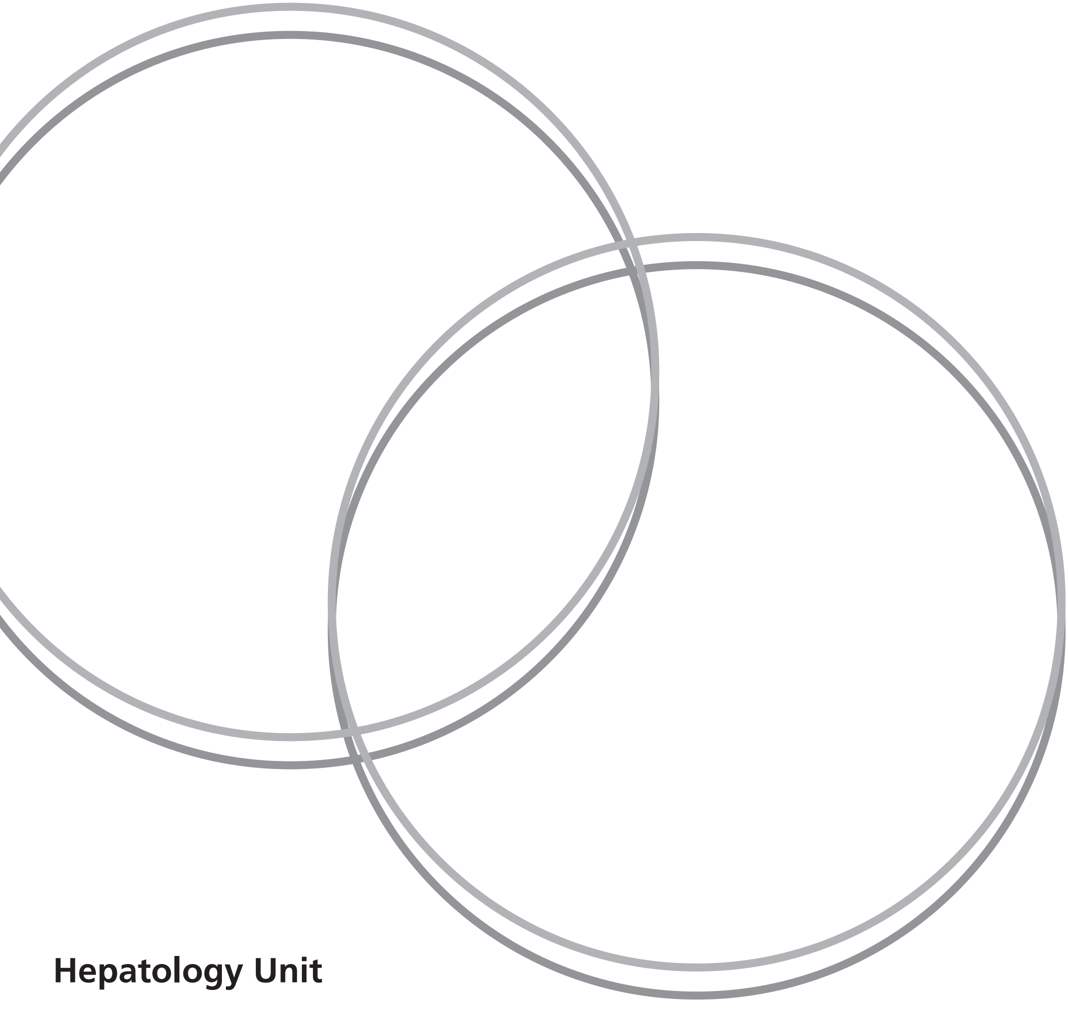
Rituximab in autoimmune liver disorders

Patient Information



Hepatology Unit

Rituximab in autoimmune liver disorders

This leaflet answers some common questions patients ask about rituximab.

Further information can be found in the information leaflet supplied by the manufacturer or from your pharmacist, liver nurse specialist or doctor.

Why have I been started on this medicine?

Rituximab is prescribed for patients diagnosed with AIH (autoimmune hepatitis) and IgG4-related disease affecting the liver, bile ducts and pancreas. These conditions are examples of immune mediated (autoimmune) liver disorders. Rituximab is unlicensed for AIH and is third line therapy for IgG4-related disease. It is sometimes used in patients who are intolerant or refractory to standard treatments such as corticosteroids and other immunomodulators.

Autoimmune liver disorders can develop when your body's own immune system mistakenly attacks the cells in your liver causes damage. No one knows why this happens. If left untreated it can lead to cirrhosis (scarring of the liver), which has a higher risk of liver cancer.

AIH may have an inherited predisposition to the disease, which is finally triggered by something in the environment. We do not, however, know what the environmental trigger is (or triggers may be). 30-50% of people diagnosed with AIH have another autoimmune condition, such as thyroid disease, rheumatoid arthritis, ulcerative colitis, or Type 1 diabetes. It is estimated that 15 to 25 per 100,000 people in Europe have AIH.

IgG4 related disease is a chronic-fibroinflammatory disorder affecting a wide range of organs. Although these are commonly the salivary glands, pancreas, and bile duct, and liver, aorta and retroperitoneum. It is a rare disease affecting an estimated 10 per 100,000 people.

Common symptoms associated with autoimmune liver disorders include fatigue, weight loss, nausea, abdominal pain, jaundice, dark urine. Because of related conditions, some people may have joint pains, diarrhoea and feel generally unwell. Most patients with well-controlled disease have no symptoms at all.

There is no cure for autoimmune liver disorders but there are effective treatments to control the disease and reduce the risk of progression including steroids and rituximab. The main goal of treatment is to stop the liver inflammation by getting your immune system back under control. We can assess this with blood tests and imaging of the liver. Around 70% of patients will relapse within 12 months if treatment is withdrawn.

How does it work?

Rituximab is a biological medicine, also known as a monoclonal antibody which suppresses inflammation in many organs including the liver, bile ducts and pancreas. It works by locking on to a protein called CD20 on the surface of a specific type of white blood cells in the body called B cells. This triggers the body's immune system to attack and remove B cells. CD20 is found in normal B-cells and abnormal B cells that occur in AIH and igG4 related disease. Once treatment is completed the body can replace the normal B -cells.

Reducing inflammation will improve your symptoms, improve your liver blood tests, reduce the degree of scarring, and help prevent long-term liver damage and liver failure.

How long does it take to work?

Rituximab can take several weeks to work; therefore you may not notice any changes to your liver condition straight away.

What dose do I take?

Rituximab is given as an intravenous infusion (a medicine given slowly into a vein using an infusion pump) through a cannula (small plastic tube) inserted into the back of your hand.

You will typically receive two infusions of 1000mg given two weeks apart ,or 500mg infusions given over 4 weeks.

You will either attend the daycase at the Nuffield Orthopaedic Centre (NOC) or the Daycase Unit at the JR Hospital, to receive the treatment. You will be asked to sign a consent form to say you agree to the risk and benefits of receiving rituximab.

The first infusion will take around 3-4 hours, slightly shorter for subsequent doses. Before each infusion you will be given an antihistamine and paracetamol to reduce you feeling unwell during the infusion. You may also be given a corticosteroid.

You will be given an alert card to carry with you so that, in an emergency, any doctors will know that you have had a rituximab infusion and that your immune system may be reduced. Always keep this with you and for a year after the infusion.

How long will I be taking it?

If you respond well to the first two doses you may continue receiving six- or twelve-monthly doses. The length and frequency of treatment will be decided by your response to it and blood test monitoring.

Steroid-free monotherapy is the goal of maintenance therapy and rituximab should enable the dose of steroid to be reduced and eventually stopped.

What are the common side effects?

Rituximab is safe and well tolerated in most people. However, rituximab has some potential side effects like any other medicine.

Common side effects include allergic rash, low blood pressure, shortness of breath, nausea, dizziness, headache, flushing, flu-like symptoms such as chills, muscle aches, or fevers, bruising and bleeding, loss of appetite, raised blood sugar levels, diarrhoea or constipation, eye infection (conjunctivitis). There is an increased risk of infections for around six to nine months after each course of treatment as your immune system will take some time to recover.

Infusion related reactions usually start within minutes of infusion starting. Your blood pressure, heart rate, respiratory rate and temperature will be monitored closely for signs of an infusion-related reaction.

Although very rare (less than 1 in 10,000 people), rituximab can cause a condition called progressive multifocal leucoencephalopathy (PML). This is a serious viral brain infection which can be fatal. You should seek medical help immediately if you notice any of the following symptoms: pins and needles, weakness or difficulty moving your face, arms or legs, shaky movements or unsteadiness, loss of vision, difficulty in speaking or changes in your behaviour or mood.

What do I do if I experience side effects?

If you experience any signs of illness or side effects especially signs if infection e.g. fever, sore throat, cough, shortness of breath, malaise, unexplained bruising, bleeding contact your GP or liver specialist team as soon as possible.

Let your liver doctor know if you develop a rash within four months of receiving rituximab.

Do I need any special checks before and after I start rituximab?

You will be under the specialist care of a hepatology/rheumatology consultant. When you are first diagnosed, you may require frequent outpatient appointments so that we can adjust your medication and monitor your disease closely. Once your disease is well-controlled, your outpatient appointments and blood tests will become less frequent. It is important that you attend your appointments and have any tests that are recommended because they are vital to your care. If you develop cirrhosis, you will have an ultrasound scan of the liver every six months. These ultrasound scans are important because people with cirrhosis have increased risk of liver cancer, and regular scans can help to detect liver cancer at an early and treatable stage.

We will do our best to keep the monitoring of your condition up to date. We strongly encourage you to become familiar with the tests you need, however, to ensure these tests happen when they should.

You will need to have blood tests to check your kidney function, liver function, full blood count and the presence of hepatitis B virus and your immunity to it.

If you have an active hepatitis B infection, you cannot be treated with rituximab. If you have been exposed to hepatitis B in the past (i.e. are HBV core positive) then we may delay your rituximab treatment until you have started some hepatitis B prophylaxis medication as rituximab increases the risk of reactivation of the hepatitis B virus. You will be closely monitored for any signs of reactivation whilst on rituximab. If treatment with rituximab is stopped then hepatitis B prophylaxis must continue for 12 months after stopping as the risk of reactivation remains for this time. Your liver team will prescribe the prophylactic medication.

If you have not had chicken pox before and come into personal contact with someone who has chickenpox or shingles, you must see a doctor as soon as possible.

You should let your liver doctor know if:

- You have had a reaction to rituximab or any other medications or vaccines in the past
- You have a current infection or have had one in the last two weeks
- You are pregnant or trying to become pregnant
- You have any significant heart or lung conditions, especially chronic infections such as bronchiectasis or tuberculosis (TB).

Do I need to take anything else during the course of rituximab treatment?

Co-trimoxazole: an antibiotic that helps prevent a particular type of lung infection called pneumocystits pneumonia (PJP). If you are considered high risk of this infection, you will be asked to take one tablet once daily and continue this for six months after stopping rituximab.

Does rituximab interfere with my other medicines?

Your blood pressure may fall when you are having rituximab. If you usually take a medicine to lower your blood pressure you may, be asked not to take it for 12 hours before having rituximab. Your blood pressure will be checked regularly throughout the infusion.

It is safe to drink alcohol in moderation whilst on rituximab, but it may aggravate the nausea.

You should avoid having ‘live’ vaccines whilst taking Rituximab e,g, Mumps, measles and rubella (MMR), yellow fever, BCG, some Typhoid vaccines, Varicella vaccines. If you require travel vaccines or your doctor, nurse or pharmacist advise that you need a vaccine always tell the healthcare professional that you are taking Rituximab. Seasonal vaccination against influenza, Pneumococcal and COVID vaccines are also recommended for adults taking rituximab and should be given at least 4 weeks before the rituximab infusion.

Is rituximab OK in pregnancy and breastfeeding?

The potential risk of rituximab to an unborn baby has not been studied.

Women – you should wait for 12 months after finishing your last rituximab treatment before trying to become pregnant. It is important that you use a reliable form of contraception whilst receiving rituximab. You should discuss with your liver doctor before trying for a baby.

It is uncertain whether rituximab is excreted in human milk, therefore you should not breastfeed if you are receiving rituximab because the drug may pass into breast milk and could be harmful to the baby. You should wait for twelve months after your last treatment before considering breastfeeding.

Men – few concerns have been raised on the use of rituximab by men who are trying for a baby. However, there is currently limited scientific data to rule out the potential risk completely. If you would like more information, please discuss this with your liver doctor.

Where can I receive more information and support?

Hepatology pharmacist:

Tel: **01865 221 523**

Hepatology Nurse advice line:

Tel: **01865 222 057**

AIH Support:

Help for those affected by Autoimmune Hepatitis: AIH Support

British Liver Trust:

British Liver Trust Helpline:

Tel: **0800 652 7330**
(10:00 to 15:00 Monday to Friday)

UK-AIH:

UK-AIH

Keep all medicines out of the reach of children.

Never give any medication prescribed for you to anyone else.

It may harm them even if their symptoms are the same as yours.

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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