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Biologic drugs (or 'biologics') are designed to act on the specific parts of your immune system which cause inflammation in your joints. Biologics are used sparingly because they are expensive – the National Institute of Health and Clinical Excellence (NICE) and equivalent rule on availability, which can vary across the UK. Biologics are given by injection or infusion, and have potential side effects, which can put some people off.

Biologic drugs do not work for everyone, but can control your disease when other treatments have not worked.

What are biologics?

There are two main types of biologics available. The first type, anti-TNFs, reduce the action of a protein (called tumour necrosis factor or TNF) produced by white blood cells to trigger inflammation. Anti-TNFs include etanercept (Enbrel), adalimumab (Humira), infliximab (Remicade), certolizumab pegol (Cimzia) and golimumab (Simponi). These drugs are not covered in this factsheet. For information on anti-TNFs see www.arthritiscare.org.uk

The second type, known simply as biologics, have been developed because there is evidence to suggest that 20-30 per cent of people with rheumatoid arthritis do not respond to anti-TNF treatment. The new drugs target different processes in the immune system from anti-TNFs.

This factsheet covers the three main biologics currently available in the UK – rituximab (MabThera), abatacept (Orencia) and tocilizumab (RoActemra). Other biologics are being considered for use in the UK but are still in the research phase.

REAL LIFE STORY

‘ I was diagnosed with rheumatoid arthritis 15 years ago. Starting on infliximab as well as methotrexate made a big difference to me within a week. Because my liver was being damaged by methotrexate, I was able to continue with infliximab by itself, but it stopped working after a few months. My consultant then put me on rituximab. This took a couple of months to take effect. I was almost fed-up waiting when suddenly my hands felt much better.

I still wear splints to protect my joints when doing the gardening. I feel a bit achy sometimes but I hardly notice. I am so pleased to be able to use my hands, and so relieved that the drug works. ’

Where are biologics available?

Biologics are not suitable for everyone and availability varies across the UK.

The Medicines and Healthcare products Regulatory Agency (MHRA) say what drug is safe to be used within the UK. Rituximab, abatacept and tocilizumab are all licensed drugs in the UK.

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NICE sets clear guidelines for which treatment should be available through the NHS in England and Wales. Health trusts are legally required to make approved treatments available when recommended by medical practitioners, and it can be very difficult for medical practitioners to get treatments if they are not NICE approved. Decisions in Northern Ireland are usually based on those of NICE. The equivalent body in Scotland is called the Scottish Medicines Consortium (SMC). All guidance lays down strict rules on eligibility, previous drug treatment, disease activity and level of response.

Rituximab, tocilizumab and abatacept are approved for use in people with rheumatoid arthritis across the UK under the conditions below.

How are biologics prescribed?

In general, you can only be prescribed a biologic drug after you have had an inadequate response to – or have an intolerance of – other disease-modifying anti-rheumatic drugs (DMARDs; for example, methotrexate), including at least one anti-TNF.

The biologic rituximab is often tried first. However, in England and Wales, NICE have provisionally ruled that you might be eligible for tocilizumab without having to first try rituximab.

You might be eligible for abatacept only if you are unable to have rituximab for medical reasons or have had to stop taking it because you had a bad reaction to it.

You will usually have two assessments at a rheumatology clinic to see if you could be eligible for treatment. These will usually be four weeks apart and use a disease activity score (DAS) to calculate how severe your arthritis is. The next steps involve assessments to check for underlying infections (or risk of infection), and your general health. You will have blood and urine tests, and a chest X-ray and tuberculosis (TB) risk assessment.

If you have had active TB in the past, repeated infections, cancer or a serious heart condition, you may not be able to have biologic drugs, but this will depend on your individual circumstances. Treatment will need to be postponed if you are pregnant or have an infection.

Once approved, it can take about two months to start treatment, but this will vary.

What are the long-term side effects of biologic drugs?

As biologic drugs are still fairly new, the long-term side effects are not known. However, once you are prescribed a biologic drug, you will have regular checkups with your doctor to monitor your progress. People on biologic drugs for rheumatoid arthritis should be asked to be put on a registry so that if there are new or unexpected side effects, doctors can be alerted immediately.

Remember that the risk of joint damage without treatment is much greater than the

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risk of side effects or infections. Discuss any concerns with your consultant and rheumatology nurse or call Arthritis Care's free helplines on 0808 800 4050.

What is rituximab (MabThera) and how does it work?

Rituximab (MabThera) is a drug which reduces a type of white blood cell (B-cell). B-cells are thought to play an important role in inflammatory arthritis when the body's immune system attacks the body's joints.

Rituximab is used to treat severe active rheumatoid arthritis, usually in combination with methotrexate.

How is it given?

Rituximab is administered in two sessions at a hospital through an intravenous infusion (drip). The first session can take five hours. You will be monitored closely during the drug administration and asked if you feel any side effects. The second session is given 14 days later and usually takes a bit less time.

The timing of the next treatment will depend on how you respond to the initial treatment – it could be 6 months or more later.

Side effects

You may be slightly more susceptible to infection after treatment. The most important thing you can do to manage a cold or flu is to rest and drink fluids. Be alert for signs that you are developing chest infection, such as severe cough, high fever, breathing problems and pain when you take a breath – see your doctor if you experience these symptoms. Your doctor will be monitoring your condition closely through regular checkups while you are taking this drug. If you think you may have an infection before treatment, even a mild one like a cold, you should tell your doctor.

Rituximab can sometimes cause a temporary reaction during an infusion so you will always be monitored and given anti-histamines to reduce any reaction.

The most common side effects for rituximab are headaches, dizziness, and a rash – but these can be treated with a steroid injection. Other common side effects are back pain, nausea, tingling of hands and feet, bleeding gums, increased urination and a runny nose. If you experience any side effects, you must contact your doctor. A few people can experience a chest or urinary tract infection.

If you experience more serious side effects such as chest pain, blood in urine or stools, or a sensation of spinning, you must immediately contact your doctor. Your rheumatology nurse/doctor will advise you further about side effects.

What is abatacept (Orencia) and how does it work?

Abatacept works by blocking the activity of T-cells, which are a type of white blood cell. It makes them inactive and stops a chain of events linked to the immune system targeting the joints.

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Abatacept is used to treat severe active rheumatoid arthritis, usually in combination with methotrexate. It is available throughout the UK in limited circumstances.

How is it given?

Abatacept is administered at a hospital through an intravenous infusion (drip). You will be monitored closely during the drug administration. The administration will take about 30 minutes every 4 weeks.

Side effects

You may be slightly more susceptible to infection after treatment. The most important thing you can do to manage a cold or flu is to rest and drink fluids. Be alert for signs that you are developing chest infection, such as severe cough, high fever, breathing problems and pain when you take a breath – see your doctor if you experience these symptoms. Your doctor will be monitoring your condition closely through regular checkups while you are taking this drug. If you think you may have an infection before treatment, even a mild one like a cold, you should tell your doctor.

Abatacept can sometimes cause a temporary reaction during an infusion so you will always be monitored and given anti-histamines to reduce any reaction.

Some common side effects of abatacept are headaches, dizziness, nausea, a cold and back pain. Other more serious side effects include: skin rash; swelling of the eyes, face, lips, tongue or throat; and shortness of breath. Your rheumatology nurse/doctor will advise you further about side effects.

What is tocilizumab (RoActemra) and how does it work?

Tocilizumab blocks interleukin-6 (a signalling substance) which helps to maintain inflammation in rheumatoid arthritis.

Tocilizumab is used to treat moderate to severe rheumatoid arthritis, usually in combination with methotrexate.

How is it given?

Tocilizumab is administered at a hospital through an intravenous infusion (drip) every four weeks. You will be monitored closely during the drug administration.

Side effects

You may be slightly more susceptible to infection after treatment. The most important thing you can do to manage a cold or flu is to rest and drink fluids. Be alert for signs that you are developing chest infection, such as severe cough, high fever, breathing problems and pain when you take a breath – see your doctor if you experience these symptoms. Your doctor will be monitoring your condition closely through regular checkups while you are taking this drug. If you think you may have an infection before treatment, even a mild one like a cold, you should tell your doctor.

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Tocilizumab can sometimes cause a temporary reaction during an infusion so you will always be monitored and given anti-histamines to reduce any reaction.

The most common side effects include: stomach pain; black stools; bloody or cloudy urine; blurred vision; body aches; and cough. Your rheumatology nurse/doctor will advise you further about side effects.

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Where can I get more information and support?

Arthritis Care is the UK's largest charity working with and for all people who have arthritis.

- Talk to someone in confidence about your arthritis by contacting our free helplines:

**0808 800 4050 (10am-4pm weekdays)
or Helplines@arthritiscare.org.uk**

- Our website has information and discussion forums where you can find support from others with arthritis:

www.arthritiscare.org.uk

- Make a contribution to our work by donating:

020 7380 6540 or online

Our information is regularly reviewed.

This factsheet was last reviewed in 2011. It will be next reviewed in 2012.

Note

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Arthritis Care across the UK

Arthritis Care UK office and England regional services:

Tel: 020 7380 6500, or email: info@arthritiscare.org.uk

Arthritis Care in Central England

Tel: 0115 952 5522

CentralEngland@arthritiscare.org.uk

Arthritis Care in North England

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