



Biologics and biosimilars

- Biologics and biosimilars are medications that can help control your overactive immune system
- They target the specific cells or proteins that are causing problems, not your whole immune system
- They provide more treatment options for people with arthritis

A new group of medications - biosimilars - has recently become available to treat conditions such as rheumatoid arthritis, juvenile arthritis and ankylosing spondylitis. This is providing more options for people living with these conditions.

So what are biologics and biosimilars? And how will this new group of medications (biotherapeutics) change the way we treat conditions that affect arthritis and musculoskeletal conditions in the future?

The immune system

To understand biologics and biosimilars - what they are and how they work – it's helpful to understand a bit about your immune system.

The role of your immune system is to identify foreign bodies (e.g. bacteria and viruses) and respond in a way that keeps you healthy from disease and infection. When your body detects the presence of foreign bodies, your immune system will launch an attack and defend your body against them. Once they've been dealt with your immune system returns to normal.

However sometimes the immune system malfunctions and attacks the healthy tissues and cells it's supposed to protect. Your immune system launches an attack, but doesn't stop, causing inflammation, pain and joint damage.

This is called autoimmunity, and conditions like rheumatoid arthritis, juvenile arthritis and ankylosing spondylitis are autoimmune conditions.

Medications

To manage this immune response, and to treat the pain and inflammation associated with it, you'll be prescribed certain medications. You may take these medications on their own, or in combination with others.

Commonly prescribed medications are:

- pain relievers (or analgesics) - for temporary pain relief
- non-steroidal anti-inflammatories (NSAIDs) - to control inflammation and provide pain relief
- corticosteroids - to quickly control or reduce inflammation
- disease-modifying anti-rheumatic drugs (DMARDs) - control your overactive immune system
- biologics and biosimilars (bDMARDs) - are biological disease-modifying drugs that also work to control your immune system, but in a much more targeted way.

Biologics

Biologics have been around for decades and include products such as insulin and vaccines. They're called biologics (or biologicals) because they've been created from a biological source (e.g. human cells). They're usually made of proteins that occur naturally in our bodies.



In the late 1990s the first biological medications for treating arthritis appeared. They worked by targeting the specific parts of the immune system that cause inflammation and tissue damage. Unlike medications such as methotrexate that suppress your immune system more broadly, biologics target the specific cells or proteins that are causing the problems.

Biologics are very expensive due to the high costs associated with developing them. That's why they aren't prescribed to everyone. They may not be the best choice in terms of cost, side effects and the availability of other effective medications.

So before you can be prescribed a biologic that has been subsidised on the Pharmaceutical Benefits Scheme (PBS), you need to meet strict criteria.

Biosimilars

The patents, or exclusive copyright, for many biologics have expired, or are about to expire. Since they're no longer protected by a patent other manufacturers can attempt to copy or duplicate the medication. This has led to the appearance of biosimilars.

Biosimilars are similar - hence the name - to biologics. They're very similar, but not the same as the original medication.

Biosimilars are created using a process of reverse engineering. That means that the manufacturer takes an existing biologic, and any published information about it, and they work backwards to figure out how to recreate the product.

Because they're created from a biological source, and using a different manufacturing process to the original, it's impossible to produce an exact duplicate. So biosimilars aren't a generic version of the biologic.

Biosimilars are a bit cheaper than biologics. By using an existing biologic as a guide, the manufacturer has saved some of the time and money that would normally be spent on developing a brand new medication.

However it's still a time-consuming and expensive process.

How do I take them?

Biologics and biosimilars may be given as an injection under the skin or an infusion into the vein. It will depend on the specific medication you've been prescribed.

Injections can be done at home. You'll be taught how to do this. Infusions are only done in a medical setting, like a hospital or clinic. Depending on the medication you've been prescribed, you may have to take it daily, weekly, fortnightly or monthly. Different medications have

different schedules. Make sure you know and understand the schedule for your specific medication.

Are there any side effects?

As far as biologics go, most people handle them really well. These medications have been around for many years, and we know how large groups of people have responded to them.

In the case of biosimilars, although they haven't been around as long, or been used on as many people, they've been tested and shown to be as safe and effective as the original biologic.

Some people may never experience any side effects, while others have mild side effects. The most common side effects that you may experience are mild pain, itching and swelling at the place you had your injection. These reactions are easily dealt with using ice or a medicated cream.

With an infusion, there's a potential for an allergic reaction. That's why you're closely monitored while you receive your infusion, and for some time afterwards.

Another side effect of these medications is they make it harder for you to fight infections. This is because they suppress your immune system. If you develop an infection, or get sick while taking these medications, see your doctor straight away.

What else do I need to know?

Medical history - before you start using a biologic or biosimilar, your rheumatologist will take your medical history. They want to make sure that you're as healthy as possible before starting the medication. You won't be able to start if you're sick or have an infection. You'll also need to be up-to-date with all of your normal vaccinations.

Your doctor may also do some tests to make sure you haven't been in contact with anyone who has had the disease tuberculosis.

Vaccinations - having a flu vaccination is important when you have a chronic condition like arthritis. It's even more important when you're taking a biologic or biosimilar because you're much more susceptible to catching the flu. A flu vaccination will help prevent this.

While using a biologic or biosimilar you can't have any live vaccinations. Common live vaccinations include measles, mumps and rubella (MMR), chickenpox (varicella), yellow fever and shingles. Live vaccinations contain a weakened form of a virus. People with a healthy immune system develop an immunity to the virus when they're given these weakened forms of it.

However because your immune system has been suppressed, live vaccines need to be avoided.

Illness and infections - while you're taking a biologic or biosimilar, you're more susceptible to germs and infections. If you develop an infection, talk with your doctor about whether this needs to be treated before you can continue taking your medication.

You should also let your doctor know straight away if you're in contact with someone who has chicken pox or shingles. You can be treated for these conditions if they're identified early.

Other medications - if you're taking any other medications or supplements - even those you've bought off the shelf in a supermarket, pharmacy or health food store - let your doctor know. Different medications and supplements can interact with each other and can make you sick. Or they can prevent your medications from working properly.

Regular check-ups - you'll need to visit your doctor regularly so they can keep an eye on how your medications are going - if they're working and if you're having any side effects. This will include regular blood tests.

Some people may need to change the biologic or biosimilar they're taking if they:

- have no response to it
- experience unacceptable side effects
- find the effectiveness of the biologic has decreased.

If this occurs, you and your doctor will discuss your options and alternative treatments.

Body piercing and tattoos - if you're wanting to get a body piercing or tattoo, talk with your doctor first. Both piercing and tattooing carry a risk of infection, and with a suppressed immune system, this can be a big problem. So before you go anywhere near a needle, get some advice from your doctor first.

Contraception - these medications are still relatively new medications, so we don't know if they're safe in pregnancy. If you're sexually active (whether you're male or female), you should talk with your doctor about contraception and always use a condom.

If you're wanting to become pregnant, speak with your doctor first.

Ask questions

You should ask your doctor any questions you have about your condition, medications and other treatments. Write them down so you don't forget, especially if you don't see your doctor very often.

Some questions you may want to ask your doctor:

- Why am I taking this medication?
- How does it work?
- Are there other choices?
- How long will I need to take it?
- What are the side effects?
- What happens if I miss a dose?
- How will I know if it's working?
- What if it doesn't work?
- Are there any long-term effects?

Substitution

Your pharmacist may ask you if you'd like to try a substitute medication. If you're taking a biologic, they may ask if you'd like to substitute it for a biosimilar.

However it's important to remember that biosimilars aren't generic versions of the original biologic. Before substituting, you should discuss this with your doctor so that you can make an informed choice.

If you've found a medication that works for you – you and your doctor may not want to risk changing it. In this case, your doctor can tick the brand substitution not permitted box on your prescription.

It's also important to know that there's not as much research about the safety of switching back and forth more than once between biologics and biosimilars. So talk with your doctor first so that you're fully informed.

Keep track

As with any medication, it's a good idea to track how you're going.

Take note and keep track of things such as:

- your medication schedule
- dosage
- side effects
- when you need to go for blood tests
- when you need to get a new prescription
- other medications and supplements you're taking.

You also might find it helpful to take a photo of the packaging your medication comes in.

Write this information in a notebook or use one of the many apps available for your smartphone.

All of the information you record will help you when you visit your doctor – especially if there's some time between your appointments. It provides an accurate record of how you've been.

Patient support programs

Many pharmaceutical companies have support programs that can give you information and support while you're taking their biologic or biosimilar. Talk with your doctor about how you can access these programs.

Where to get help

- Your doctor
- Your specialist
- Your pharmacist
- Musculoskeletal Australia
www.msk.org.au
MSK Help Line: 1800 263 265

How we can help

Call our MSK Help Line and speak to our nurses. Phone 1800 263 265 or email helpline@msk.org.au.

We can help you find out more about:

- arthritis and musculoskeletal conditions
- ways to live well with these conditions
- managing your pain
- upcoming webinars, seminars and other events.

More to explore

- Better Health Channel
www.betterhealth.vic.gov.au
- Australian Government—Dept of Health
www.health.gov.au/internet/main/publishing.nsf/Content/biosimilar-what-are-biosimilar-medicines
- Australian Rheumatology Association - Medication Information
<https://rheumatology.org.au/patients/medication-information.asp>
- NPS MedicineWise www.nps.org.au
Medicines Line - 1300 633 424 - 9am to 5pm weekdays for information on medications
Adverse Medicine Events Line - 1300 134 237 - 9am to 5pm weekdays to report a problem with medicines, medical devices or vaccines
MedicineWise app - Available through Google Play and the App Store