Information about the Tocilizumab (Actemra®) Shortage

There is currently a [global shortage of tocilizumab (Actemra®)](https://www.tga.gov.au/alert/shortages-tocilizumab-actemra-medicines). As a result [tocilizumab](https://arthritisaustralia.com.au/medication-search/tocilizumab/) products are currently in limited supply in Australia. If you are currently taking tocilizumab (Actemra®), these shortages may affect your treatment.

**Update 21 December 2021:**

**IV tocilizumab patients:**

A small shipment of 400mg IV tocilizumab has arrived in Australia and will be available to some consumers shortly.

Following supply modelling and collaboration between the TGA, Roche Australia, the Australian Rheumatology Association and Arthritis Australia, hospitals will receive increased allocations of IV tocilizumab, however these will still be significantly less than pre-pandemic levels.

The Australian Rheumatology Association have published revised [clinical guidance](https://rheumatology.org.au/For-Patients/Medication-Information/Tocilizumab-Shortage) that includes information about consumers who can now access tocilizumab:

**Systemic juvenile idiopathic arthritis (sJIA) patients and polyarticular juvenile idiopathic arthritis (pJIA) consumers**

* + - Consumers undergoing IV tocilizumab treatment for sJIA and pJIA may resume their normal dosing regimen.
		- Consumers with sJIA and pJIA can be initiated on IV tocilizumab if required.

**Adult rheumatoid arthritis consumers**

* + - Adult consumers who have been continued on IV tocilizumab treatment for rheumatoid arthritis during the shortage may resume their normal dosing regimen if dosing intervals have been increased during the shortage.
		- For those adult consumers who were previously on IV tocilizumab and were switched to alternative biologic or targeted synthetic agent due to the tocilizumab shortage, but are now experiencing flare requiring prednisolone, these consumers may resume IV tocilizumab.
		- We continue to recommend against initiation of adult RA consumers onto IV tocilizumab.
	+ Consumers should contact their rheumatologists for further advice.
	+ Any changes to the availability of IV tocilizumab products will be communicated to consumers and rheumatologists.

**Subcutaneous (SC) tocilizumab patients**

Supply of subcutaneous tocilizumab is building back up to normal supply from January 2022. Supply of the ACTPen and Prefilled Syringe may still be variable at times

To assist consumers, the tocilizumab [Serious Scarcity Substitution Instrument (SSSI)](https://www.legislation.gov.au/Details/F2021L01852) has been extended until 30 April 2022. The SSSI makes sure that pharmacists can offer adult consumers whichever subcutaneous presentation is available at the pharmacy without the need for a new script.

In line with guidance from the Australian Rheumatology Association:

* + initiation and ongoing use of SC tocilizumab should be reserved for conditions with no alternatives (Giant Cell Arteritis and Juvenile Idiopathic Arthritis).
	+ adult RA consumers should not be initiated onto SC tocilizumab unless alternate therapy is not appropriate.

**Frequently Asked Questions:**
**Am I eligible for IV tocilizumab?**

At this time, IV tocilizumab is available to consumers with:

* Systemic Juvenile Idiopathic Arthritis
* Polyarticular Juvenile Idiopathic Arthritis
* Rheumatoid arthritis who have stayed on tocilizumab with extended dosing intervals
* Rheumatoid arthritis who were previously on IV tocilizumab and were switched to alternative biologic or targeted synthetic agent due to the shortage, but are now experiencing flare requiring prednisolone
* Cytokine release syndrome

**My doses of tocilizumab have been spaced out but I am having flares - how can I access more tocilizumab?**

Contact your rheumatologist to discuss your treatment.

**I have been switched to another medicine but it’s not working well for me – can I go back to using tocilizumab?**

You may be eligible for IV tocilizumab – contact your rheumatologist to discuss your treatment

**My hospital doesn’t have enough tocilizumab for my treatment. What can I do?**

Your rheumatologist can contact Roche Australia if you are a patient that fits the Australian Rheumatology Association’s [clinical guidelines](https://rheumatology.org.au/For-Patients/Medication-Information/Tocilizumab-Shortage)

Why is there a shortage?

The shortage is due to increased global demand for tocilizumab for use in people who are severely ill with COVID-19.  ­­

Who is affected?

Anyone who is taking tocilizumab is likely to be affected by the shortage. In Australia, tocilizumab is used to treat children and adults with the following conditions:

* rheumatoid arthritis (RA)
* systemic juvenile idiopathic arthritis (sJIA)
* polyarticular juvenile idiopathic arthritis (pJIA)
* giant cell arteritis (GCA)
* cytokine release syndrome (CRS).

How long is the shortage expected to last?

The supply of all tocilizumab products is expected to remain limited until the first quarter of 2022.

Which products are affected by the shortage?

All tocilizumab products are affected:

* There is only extremely limited stock of the intravenous (IV) presentations used for infusions
* Supply of the pre-filled syringes and ACTPen Autoinjector is limited. However existing patients should be able to access one or the other.

What steps are being taken to manage the shortage?

The Therapeutic Goods Administration (TGA) is working with Roche and other stakeholders to manage supply to reduce the impact of the current shortage on those taking tocilizumab.

Measures have been taken to preserve stock for children with sJIA and pJIA, and for people with GCA or CRS who have no alternative treatments, and for people who are unable to switch medicines.

What will happen with my treatment?

It is important to talk to your rheumatologist to discuss managing your treatment during this shortage.

If you have sJIA, pJIA or GCA, you should be able to continue on tocilizumab.

If you have RA and are on IV tocilizumab for infusion, your rheumatologist is likely to prescribe a different medicine for you.

Your prescriber may also suggest spacing out your infusions/injections, e.g. from weekly to fortnightly.

What alternative treatments are available?

Alternative biologic treatments are available for people with RA.  If you need to switch medicines, your rheumatologist can advise the best alternative treatment for you.

What if I have already tried 3 or 4 biologics that have not worked for me?

New treatment options have become available in recent times which may be effective.  You should discuss options with your rheumatologist.

What if my pharmacist doesn’t have stock?

If you have a script for the prefilled syringe or the ACTPen, you should contact your pharmacist well before your supply runs out, to order your medication.

Your pharmacist should be able to order **either** the prefilled syringe **or** the ACTPen. If your pharmacist says they have no stock, ask them to continue to check with their wholesaler directly (rather than through a portal), or to try a different wholesaler.

If you are an adult and use the prefilled syringe or ACTPen autoinjector you might need to swap between these two products.  Ask your rheumatologist, GP or rheumatology nurse to show you how to use both types in case you need to swap.  Alternatively, contact Roche Medical Information on 1800 233 950 or australia.medinfo@roche.com  for information on how to use these products.

If I need to change treatment, what will happen if I don’t do as well on the new treatment?

Talk to your rheumatologist as soon as possible to review your treatment if you are not doing well on the new treatment.

It may help to talk to your rheumatology team in advance to develop a [flare action plan](https://www.nps.org.au/assets/NPS/pdf/NPS2347_bDMARDs_Flares_v4-v2-jg-120121-INT-ACC.PDF).

For arthritis information and access to local support services, call the Arthritis Infoline on 1800 011 041 or contact the organisations listed below.

If I don’t do well on the new treatment, will that affect my future eligibility for biologics?

If you do not respond to the new treatment, this will not count as a ‘fail’ unless the alternative treatment continues for longer than 16 weeks.

Will I be able to go back to tocilizumab when supply returns to normal?

You will be able to resume tocilizumab treatment when supply returns to normal.

Will I be able to stay on the new treatment if that works for me?

You will be able continue on the new treatment if it works for you.

***[Download these FAQs](https://arthritisaustralia.com.au/wordpress/wp-content/uploads/2021/09/210914-Tocilizumab-Shortage-Consume-FAQs_Final.pdf%22%20%5Ct%20%22_blank)***

Further information and support

* Arthritis Australia: Infoline 1800 011 041 [arthritisaustralia.com.au](http://www.arthritisaustralia.com.au/)
* Musculoskeletal Australia: Help Line: 1800 263 265 [msk.org.au](http://www.msk.org.au/)
* CreakyJoints Australia <https://creakyjoints.org.au/>
* Therapeutic Goods Administration <https://www.tga.gov.au/alert/shortages-tocilizumab-actemra-medicines>
* Roche Medical Information: 1800 233 950 or medinfo@roche.com
* PBS Arrangements for tocilizumab shortage: <https://www.pbs.gov.au/info/news/2021/08/pbs-arrangements-for-tocilizumab-shortage> and <https://www.pbs.gov.au/info/news/2021/08/Pharmacist-Substitution-of-PBS-Medicines>

Useful links for Pharmacists

* Information for pharmacies can be found on the TGA website [here](https://www.tga.gov.au/sites/default/files/acetemra-shortage-instructions-for-pharmacies.pdf) and as a downloadable pdf [here](https://rheumatology.org.au/Portals/2/Documents/Public/Patients/Medication_Information/Tocilizumab%20Shortage/acetemra-shortage-instructions-for-pharmacies.pdf?ver=2021-09-22-135932-297)
* Please note that pharmacists will need to call wholesalers to order tocilizumab. Wholesaler portals will likely show zero stock quantity for both subcutaneous medicines, even if they are available.

**Additional useful links**

* **TGA, ARA and Arthritis Australia Joint Statement on the tocilizumab shortage**
	+ Version 2 [28 September 2021](http://www.tga.gov.au/sites/default/files/tocilizumab-actemra-shortage-patient-management.pdf)
	+ Version 1 [4 August 2021](https://rheumatology.org.au/Portals/2/Documents/Public/Patients/Medication_Information/tocilizumab-actemra-shortage-patient-management.pdf?ver=2021-08-25-174028-533)
* This statement provides recommendations on the management of patients on tocilizumab during the shortage
* [Serious Scarcity Substitution Instrument (SSSI) for tocilizumab 6 Aug 2021](https://rheumatology.org.au/Portals/2/Documents/Public/Patients/Medication_Information/SSSI_tocilizumab.pdf?ver=2021-08-25-174028-630)
	+ This instrument allows for pharmacists to substitute the SC formulations of tocilizumab without the need to contact the prescriber
* Further information can be found on the TGA website [here](https://www.tga.gov.au/alert/shortages-tocilizumab-actemra-medicines)
* PBS Arrangements for tocilizumab shortage can be found [here](https://www.pbs.gov.au/info/news/2021/08/pbs-arrangements-for-tocilizumab-shortage)
* Roche Medical Information can be contacted on 1800 233 950