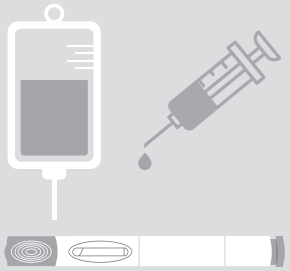
ACTEMRA
tocilizumab

Roche

tocilizumab

ACTEMRA® SUPPLY UPDATE:

SEPTEMBER 2021



Dear Pharmacist,

Roche is currently experiencing shortages of multiple presentations of ACTEMRA® (tocilizumab) in Australia. This is due to a global demand for ACTEMRA that has increased significantly in response to the COVID-19 pandemic.

While the supply of ACTEMRA IV is extremely low, we would like to confirm that ACTEMRA pre-filled syringes (PFS) and ACTEMRA pre-filled pens (ACTPen) continue to be available from wholesalers. The limited supply of ACTEMRA subcutaneous (SC) formulations caters to the needs of *existing* patients.

Roche understands the difficulties that the ACTEMRA shortage has caused to many patients and we are continuing to work closely with the Therapeutic Goods Administration (TGA), the Australian Rheumatology Association (ARA) and Arthritis Australia to minimise impact on patients. Please refer to the TGA website (https://www.tga.gov.au/media-release/joint-statement-supply-allocations-intravenous-tocilizumab-actemra-during-serious-shortage) for a joint statement on patient management and supply allocations of ACTEMRA.

Roche is also collaborating with wholesalers to prevent stockpiling of ACTEMRA SC formulations and ensure that the constrained supply is managed appropriately during the next few months.

- **All existing patients, can still access supply of ACTEMRA SC.**
- In line with guidance from the TGA, the ARA and Arthritis Australia, **prescribers should delay initiating any new rheumatoid arthritis patients on ACTEMRA SC,** except where no alternatives or no suitable alternatives are available.[1]
- Effective 7 August 2021 until 31 December 2021, the TGA has deemed the ACTEMRA PFS and ACTPen to be substitutable medicines, interchangeable at the pharmacy level for patients over 18 years of age when Serious Scarcity Substitution Instruments (SSSIs) conditions (https://www.tga.gov.au/alert/tocilizumab-actemra-serious-scarcity-substitution-instrument) are met.[2]
- Pharmacists are requested to provide patients who need to switch between SC formulations with ACTEMRA Consumer Medicine Information (www.roche-australia.com/productinfo/actemra) and QR codes (see below) to access educational videos. Some patients may need to be referred to their rheumatology specialist, nurse or general practitioner for instructions on how to switch between formulations.[1]

ACTPen® video

Pre-filled syringe video

Please note that pharmacies may experience a slight delay in fulfilment of ACTEMRA SC orders and the following approach is recommended.

1. Check wholesaler for stock levels (portal may not show the quantity of stock).
2. Contact the wholesaler if zero stock is shown on the portal.
3. Continue to contact your wholesaler for updates on stock levels as stock levels can fluctuate daily.

We are allocating stock to wholesalers on a weekly basis in accordance with historical demand. Pharmacists are advised to continue contacting their wholesaler for updates as we can confirm that we do not have any influence or visibility over wholesaler supply of ACTEMRA to pharmacies.

Kind regards,

ACTEMRA Team Australia

If you have any questions contact Roche Medical Information on 1800 233 950 or at www.medinfo.roche.com/australia

To receive emailed updates on this rapidly evolving situation simply scan the QR code opposite and fill in your consent for us to contact you.

Please review Product Information before prescribing, available at www.roche-australia.com/productinfo/actemra
ACTEMRA is listed on the PBS for certain indications.
Refer to the PBS schedule for further details.

Roche product vigilance: To report a suspected side effect or product complaint associated with the use of a Roche product, visit www.medinfo.roche.com/australia or contact Roche Patient Safety at australia.safety@roche.com

MINIMUM PRODUCT INFORMATION Actemra® (tocilizumab) Solution for subcutaneous injection (SC formulation); concentrated solution for intravenous infusion (IV formulation) **Indications:** ***Rheumatoid arthritis (RA) (SC and IV formulations)*** Moderate to severe active RA in adult patients in combination with methotrexate (MTX) or other non-biological disease-modifying anti-rheumatic drugs (DMARDs) in case of either an inadequate response or intolerance to previous therapy with one or more DMARDs; moderate to severe active RA in adult patients with poor prognostic factors in combination with MTX in those not previously treated with MTX. In these 2 patient groups Actemra can be used as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. Actemra has been shown to inhibit the progression of joint damage in adults, as measured by X-ray, when given in combination with MTX. ***Giant Cell Arteritis (GCA) (SC formulation only)*** Treatment of GCA in adult patients. ***Polyarticular juvenile idiopathic arthritis (pJIA) (SC and IV formulation)*** Moderate to severe active pJIA in patients 2 years of age and older who have had an inadequate response to or intolerance to MTX. Actemra can be given alone or in combination with MTX. ***Systemic juvenile idiopathic arthritis (sJIA) IV formulation:*** active sJIA in patients 2 years of age and older. ***SC formulation:*** active sJIA in patients 1 year of age and older. Actemra IV and SC can be given alone or in combination with MTX. ***Cytokine Release Syndrome (CRS) (IV formulation only)*** Treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 2 years of age and older. **Dosage and Administration:** Treatment should be initiated by healthcare professionals experienced in managing these conditions. Dose modification recommended for liver enzyme abnormalities, low absolute neutrophil count and low platelet count. **Adult RA:** ***IV formulation:*** 8 mg/kg body weight (BW) given once every 4 weeks. Doses > 800 mg per infusion not recommended for individuals whose BW is > 100 kg. ***SC formulation:*** 162 mg once every week. **GCA:** Recommended dose is 162 mg once every week, with tapering glucocorticoids. Dose of 162 mg once every other week, with tapering glucocorticoids, may be prescribed based on clinical considerations. **CRS:** 8 mg/kg for patients ≥ 30 kg or 12 mg/kg for patients < 30 kg. **pJIA:** ***IV formulation:*** 10 mg/kg for patients < 30 kg BW or 8 mg/kg for patients ≥ 30 kg BW once every 4 weeks. ***SC formulation:*** 162 mg once every 3 weeks for patients < 30 kg BW or 162 mg once every 2 weeks for patients ≥ 30 kg BW. sJIA: IV formulation: 12 mg/kg for patients < 30 kg BW or 8 mg/kg for patients ≥ 30 kg BW once every 2 weeks. SC formulation: 162 mg once every two weeks for patients < 30 kg BW or 162 mg once every week for patients ≥ 30 kg BW. **General dosing instructions** ***IV formulation:*** During infusion, and for 30 minutes post-infusion, monitor patients for any signs or symptoms of a hypersensitivity reaction. ***SC formulation:*** At least first injection under the supervision of a healthcare professional in a facility equipped to manage serious hypersensitivity reactions. The pre-filled syringe with needle safety device and intravenous formulation can be used to treat paediatric patients of all approved ages. The pre-filled pen (ACTPen) should not be used to treat children and adolescent patients < 12 years of age. **Contraindications:** Known hypersensitivity to any component of the product or with a history of any reaction consistent with hypersensitivity to any component of the product, Chinese hamster ovary cell products or other recombinant antibodies; active, severe infections. **Precautions:** Serious, sometimes fatal, infections have been reported; caution in patients with a history or predisposition to infection. Diverticular perforation reported; caution in patients with GI ulceration. Screen for latent tuberculosis prior to treatment. Do not give live and live attenuated vaccines concurrently with Actemra; perform vaccinations prior to treatment. Serious hypersensitivity reactions, including anaphylaxis, including fatalities with IV formulation, reported. If serious hypersensitivity reaction or anaphylaxis occurs, stop administration immediately and permanently discontinue. Viral reactivation reported. Hepatic disease including raised AST/ALT and serious drug induced liver injury; caution with patients with hepatic disease or impairment. Haematological abnormalities reported; see full PI for guidance on patient initiation. Elevated lipid levels have been reported. Regularly assess AST/ALT, haematological counts and lipid levels. Increased risk of cardiac disorders in RA patients. Monitor for symptoms of central demyelination. Increased risk of malignancy in RA patients. Patients receiving immunosuppressive therapy are at increased risk of developing skin cancer (melanoma and non-melanoma). Periodic skin examination is recommended for all patients who are at increased risk for skin cancer and exposure to sunlight and UV light should be limited by wearing protective clothing and using a sunscreen with a high protection factor. Not for use with other biological agents. Pregnancy Category C. Caution with breast-feeding mothers. Patients experiencing dizziness should not drive or use machines until resolved. Suppression of CYP450 expression may be reversed with Actemra. Monitor patients taking medicines metabolised via CYP450s as dose adjustment may be necessary. ***sJIA:*** Macrophage activation syndrome (MAS) may develop in sJIA patients. Actemra has not been studied in patients with active MAS. ***Paediatric Use:*** The pre-filled syringe with needle safety device and intravenous formulation can be used to treat paediatric patients of all approved ages. The pre-filled pen (ACTPen) should not be used to treat children and adolescent patients < 12 years of age. **Adverse Reactions:** ***Common (≥ 2%):*** upper respiratory tract infections, nasopharyngitis, headache, hypertension, cough, increased ALT/AST, diarrhoea, back pain, peripheral oedema, dizziness, bronchitis, rash, infusion reaction, mouth ulceration, abdominal pain upper, gastritis. ***Infrequent (< 2%):*** cellulitis, oral herpes simplex, herpes zoster, diverticulitis, stomatitis, gastric ulcer, pruritus, urticaria, weight increased, total bilirubin increased, leucopenia, neutropenia, hypercholesterolaemia, hypertriglyceridaemia, hypersensitivity reaction, dyspnoea, conjunctivitis, nephrolithiasis, hypothyroidism. ***Infections:*** Reported serious infections, some fatal, include pneumonia, cellulitis, herpes zoster, gastroenteritis, diverticulitis, sepsis, bacterial arthritis, opportunistic infections. ***GI perforation:*** Reported uncommonly primarily as a complication of diverticulitis, including generalised purulent peritonitis, lower GI perforation, fistula and abscess. ***SC formulation:*** consistent safety profile to IV formulation, with higher frequency of injection site reactions. ***pJIA, sJIA:*** adverse reactions are similar in type to those seen in RA patients. ***Post-marketing:*** Anaphylaxis, Stevens-Johnson Syndrome, hypofibrinogenemia, drug-induced liver injury, hepatitis, hepatic failure, jaundice, interstitial lung disease, pancytopenia. Please review the full Product Information before prescribing, available from Roche Products Pty Limited (www.roche-australia.com/productinfo/actemra). Date of preparation: 3 April 2020.

If you would like to request access to your *personal information* held by Roche; request an amendment or correction of your *personal information* held by Roche; ask us to remove your *personal information* from our system; ask us questions about, or request a copy of, our Privacy Policy; or make a complaint, please email us at australia.privacy-request@roche.com or write to the Privacy Officer, Roche Products Pty Limited, Level 8, 30-34 Hickson Road, Sydney NSW 2000. **References:**
1. Therapeutic Goods Administration, Dept. of Health, Aust. Government. Joint statement: Supply allocations of intravenous tocilizumab (Actemra) during serious shortage. Available at: https://www.tga.gov.au/media-release/joint-statement-supply-allocations-intravenous-tocilizumab-actemra-during-serious-shortage (Accessed 20/09/21). 2. Therapeutic Goods Administration, Dept. of Health, Aust. Government. Tocilizumab (Actemra) Serious Scarcity Substitution Instrument. Available at: https://www.tga.gov.au/alert/tocilizumab-actemra-serious-scarcity-substitution-instrument (Accessed 20/09/21). Further information is available on request from Roche Products Pty Limited, ABN 70 000 132 865, Level 8, 30-34 Hickson Road, Sydney NSW 2000. Medical Information: www.medinfo.roche.com/australia or 1800 233 950. ®Registered Trademark EMVACT1637 M-AU-00001051 PreparedSep21