3 September 2021
EMA/472078/2021 rev.1[1]

Shortage of RoActemra (tocilizumab)
Pre-filled syringe and pre-filled pen, solution for subcutaneous injection (162 mg)
Concentrate for solution for infusion (20 mg/ml)

Indication	RoActemra (tocilizumab) is used to treat adults with rheumatoid arthritis or giant cell arteritis, children from 1 year of age with active systemic juvenile idiopathic arthritis, and children from 2 years of age with juvenile idiopathic polyarthritis. RoActemra can also be used in adults and children from 2 years of age for the treatment of severe or life-threatening cytokine release syndrome (CRS) caused by chimeric antigen receptors (CAR) T-cell medicines.
Reason for shortage	The company holding the marketing authorisation is facing an increase in demand for RoActemra which outweighs current production capacities. This will lead to a shortage of RoActemra in Member States.
Member States affected	The shortage may affect all Member States in which the product is marketed. Currently the shortage affects EU Member States as follows: • RoActemra 162 mg solution for injection in pre-filled syringe/ pre-filled pen: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Estonia, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Norway, Portugal, Romania, Slovakia, Slovenia, Sweden, the Netherlands • RoActemra 20 mg/ml concentrate for solution for infusion (intravenous use): Austria, Belgium, Bulgaria, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, the Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain This information may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.

1 This document was modified on 14 September 2021 to update the list of Member States affected by the shortage of RoActemra 20 mg/ml concentrate for solution for infusion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2021. Reproduction is authorised provided the source is acknowledged.

Shortage of RoActemra (tocilizumab)
Pre-filled syringe and pre-filled pen, solution for subcutaneous injection (162 mg) Concentrate for solution for infusion (20 mg/ml)

Information to healthcare professionals

- An increase in demand for RoActemra may lead to a temporary supply shortage of RoActemra 162 mg solution for injection in pre-filled syringe/ pre-filled pen for subcutaneous use (RoActemra s.c.) and RoActemra concentrate for solution for intravenous infusion (RoActemra i.v.)

- Interrupting treatment with RoActemra when used for rheumatoid arthritis (RA) (adults), giant cell arteritis (GCA) (adults), polyarticular juvenile idiopathic arthritis (pJIA) or systemic juvenile idiopathic arthritis (sJIA) may lead to a disease flare up (increased disease activity/worsening symptoms)

- It is therefore important that you reassess the patient's current overall disease condition, treatment regimen and potential risk of flare and consider an alternative treatment if RoActemra is not available.

- If the patient is using RoActemra s.c., you should also consider the number of unused RoActemra pre-filled syringes/pens that the patient has in their possession.

- For patients with **RA, pJIA and sJIA:**
  - If RoActemra s.c. is out of supply, start RoActemra i.v. around 2 weeks after the last RoActemra s.c. injection and re-introduce RoActemra s.c. after the shortage has been resolved (next s.c. dose can be given at scheduled i.v. dose).
  - For RA, sarilumab s.c. (known as Kevzara) is also authorised; consider whether switching the patient to this medicinal product may be appropriate.
  - If i.v. is out of supply, start RoActemra s.c. at the next scheduled i.v. dose. Once the shortage has been resolved, RoActemra i.v. can be reintroduced around 2 weeks after the last s.c. injection.
  - If neither RoActemra s.c. nor i.v. is available, or at your discretion: consider adding/increasing the dose of conventional/biological/targeted oral DMARDs and/or glucocorticoids.

- **For GCA**: as RoActemra i.v. is not approved for GCA, if RoActemra s.c. is out of supply, you may consider restarting or increasing the dose of other treatments (e.g. corticosteroids).

	• **For CAR-T-cell-induced CRS**: as only RoActemra i.v. is approved for CRS, if the i.v. formulation is out of supply please refer to CRS treatment guidance for potential alternatives. • In some circumstances, patients may have to attend their hospital/clinic to receive alternative treatment. • A direct healthcare professional communication (DHPC) will be sent to healthcare professionals. The DHPC is also available on the EMA website. • Additional advice may be available from the national competent authority.
Information to patients	• An increase in demand for RoActemra has led to a temporary shortage of RoActemra pre-filled syringe or pen (for injection under the skin (subcutaneous injection)) and RoActemra concentrate for solution for infusion (given by a drip into a vein). • Stopping treatment with RoActemra could lead to worsening of your symptoms (disease flare up). Your doctor will assess your overall disease condition and potential risk of flare up and consider a treatment alternative if RoActemra is not available. • If you use RoActemra pre-filled syringes or pens, let your doctor know how many you have left. • Depending on the use, your doctor may switch your treatment to either the pre-filled pen/syringe or the concentrate for solution for infusion, chose another medicine or increase the dose of a medicine you are already taking. • In some circumstances you may have to attend the hospital to receive alternative treatment. • Additional advice may be available from the national competent authority.
Status	Ongoing