

18 March 2022



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**RE: Shortage of the following products:
ORENCIA abatacept (rch) 125 mg single dose ClickJect
prefilled autoinjector (AUST R 236039) and alternative
supply arrangement under Section 19A of the *Therapeutic
Goods Act*.**

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector (AUST R 236039)** LINK has arranged the supply of an alternative product, **ORENCIA 125 mg solution for injection in pre-filled pen (ClickJect)** registered and marketed in *Germany*.

ORENCIA 125 mg solution for injection in pre-filled pen (ClickJect) is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **31 July 2022**.

ORENCIA 125 mg solution for injection in pre-filled pen (ClickJect) is indicated for:

ORENCIA in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an insufficient response or intolerance to other disease modifying anti-rheumatic drugs (DMARDs), such as methotrexate or tumour necrosis factor (TNF) blocking agents. A reduction in the progression of joint damage and improvement in physical function have been demonstrated during combination treatment with ORENCIA and methotrexate.

ORENCIA in combination with methotrexate is also indicated in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

ORENCIA is indicated for reducing signs and symptoms in paediatric patients 6 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). ORENCIA may be used as monotherapy or concomitantly with methotrexate (MTX). (There is no clinical trial data for the use of ORENCIA subcutaneous formulation in children, therefore its use in children cannot be recommended.)

ORENCIA is indicated for the treatment of active psoriatic arthritis (PsA) in adults when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. ORENCIA can be used with or without non-biologic DMARDs.

ORENCIA should not be administered concurrently with other biological DMARDs (eg, TNF inhibitors, rituximab, or anakinra)

The s19A approved German product is identical in active ingredient, strength and excipient ingredients to the Australian registered product.

Please refer to the Australian Product Information for **ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector (AUST R 236039)** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **ORENCIA 125 mg solution for injection in pre-filled pen (ClickJect)**.

Healthcare professionals are reminded that the use of ORENCIA subcutaneous formulations is not recommended in children.

ORENCIA 125 mg solution for injection in pre-filled pen (ClickJect) is registered in **Germany**. The active ingredient, strength and dosage form included on the pen label are in German. However, as the storage conditions for **ORENCIA 125 mg solution for injection in pre-filled pen (ClickJect)** is also written in German, Healthcare professionals are reminded:

- to store the product in a refrigerator (2°C - 8°C). Do not freeze; and
- keep the product in the original package in order to protect from light.

An English copy of the package insert is also provided with each product in a zip lock bag.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **ORENCIA 125 mg solution for injection in pre-filled pen (ClickJect)** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector (AUST R 236039)**.

Yours sincerely,



Charlotte Griffin

Medicine Access Associate