ORENCIA®
(abatacept)

ORENCIA FOR ADULT RHEUMATOID ARTHRITIS

A guide to share with your GP

SC Injection for subcutaneous use

IV Infusion for intravenous use

This patient has been prescribed ORENCIA in combination with methotrexate for the treatment of moderate to severe rheumatoid arthritis. ORENCIA is a biologic disease-modifying antirheumatic drug (DMARD) that acts by modulating T-cell activation.

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ORENCIA INDICATION FOR ADULT RHEUMATOID ARTHRITIS

ORENCIA (abatacept) 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 antirheumatic 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 SHOULD NOT BE ADMINISTERED TO PATIENTS WITH:

- Known hypersensitivity to ORENCIA or any of its components
- Severe infections such as sepsis, abscesses, tuberculosis and opportunistic infections
- Other biologic DMARDs (e.g. TNF inhibitors, rituximab or anakinra) or JAK inhibitors (e.g. tofacitinib or baricitinib).

CONSIDERATIONS AND PRECAUTIONS

Infections

Treatment with agents that affect the immune system such as ORENCIA increases a patient's risk of infection. Physicians should exercise caution in patients with a history of recurrent infections; underlying conditions that may predispose them to infections; or chronic, latent or localised infections. Patients who develop a new infection while undergoing treatment with ORENCIA should be monitored closely.

Administration of ORENCIA should be discontinued if a patient develops a serious infection.

Malignancies

The possibility exists for drugs that affect the immune system, including ORENCIA, to affect host defences against malignancies. The incidence rate of observed malignancies in double-blind and open-label trials with ORENCIA was consistent with that expected in an age- and gender-matched rheumatoid arthritis population.

Hypersensitivity

Patients were not required to be pre-treated to prevent hypersensitivity reactions. The events of hypersensitivity, anaphylaxis and drug hypersensitivity were uncommonly reported.

Use in patients with chronic obstructive pulmonary disease (COPD)

Patients with COPD treated with ORENCIA developed adverse events more frequently than those treated with placebo, including COPD exacerbations, cough, rhonchi and dyspnoea. Use of ORENCIA in patients with rheumatoid arthritis and COPD should be undertaken with caution and such patients should be monitored for worsening of their respiratory status.

Immunisations

Live vaccines should not be given concurrently with ORENCIA or within 3 months of its discontinuation. Drugs that affect the immune system, including ORENCIA, may blunt the effectiveness of some immunisations.

Laboratory evaluations

No special laboratory evaluations are necessary in addition to careful medical management and supervision of patients.

Concomitant therapy

It is important to continue taking methotrexate to get the maximum benefit from ORENCIA. Concomitant therapies including corticosteroids, salicylates, non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics may be used during treatment with ORENCIA.

Biologic DMARDs: concurrent administration of ORENCIA and other biologic DMARDs has been associated with an increased risk of serious infections, and is not recommended. If switching from other biologic DMARDs to ORENCIA therapy, patients should be monitored for signs of infection.

Blood glucose testing

Parenteral drug products containing maltose can interfere with the readings of blood glucose monitors and result in falsely elevated blood glucose readings on the day of infusion.

ORENCIA injections for intravenous use contain maltose; therefore, patients that require blood glucose monitoring should be advised to consider methods that do not react with maltose.

ORENCIA injections for subcutaneous use do not contain maltose; therefore, patients do not need to alter their glucose monitoring.

Pregnancy and lactation

ORENCIA is Category C. The safe use of ORENCIA during pregnancy has not been established and the use of ORENCIA during pregnancy is not recommended. It is not known whether ORENCIA is excreted in human milk or absorbed systemically after ingestion; women on ORENCIA should not breastfeed.

Please discuss with the treating rheumatologist if your patient on ORENCIA develops any symptom or signs suggestive of serious side-effects.

BLOOD TESTS FOR ARTHRITIS

No blood test can definitively diagnose rheumatoid arthritis. However, they can help to confirm a diagnosis and monitor disease severity and response to treatment.

What tests are used?

Testing can be performed for different antibodies.

Rheumatoid factor (RF)

Results of this test are positive in about 80 per cent of people with rheumatoid arthritis, although it can take many years before it becomes positive. Levels can vary, and test results may be negative in the early stages of the disease or during remission. Also, RF antibodies can be present in the blood of people who do not have the disease.

Anti-citrullinated protein antibody (anti-CCP/ACPA)

Results of this test are positive in about 60 per cent of people with rheumatoid arthritis, including some who

are RF negative. The presence of these antibodies is associated with a more aggressive course of the disease. Early treatment is recommended and if the results of anti-CCP/ACPA testing are positive, it is important to see a rheumatologist as quickly as possible.

Other common blood tests

Erythrocyte sedimentation rate (ESR)
This test measures the level of inflammation in the body. A high ESR is indicative of greater levels of inflammation but it does not pinpoint exactly where or what is causing the inflammation.

C-reactive protein (CRP)
This test measures the level of inflammation in the body. A high or increasing CRP suggests acute infection or inflammation. If the CRP drops, it can suggest that inflammation is reducing. Like the ESR, the CRP test is not specific enough to diagnose a particular type of arthritis or disease.

ORENCIA SUBCUTANEOUS INJECTION DOSAGE AND ADMINISTRATION

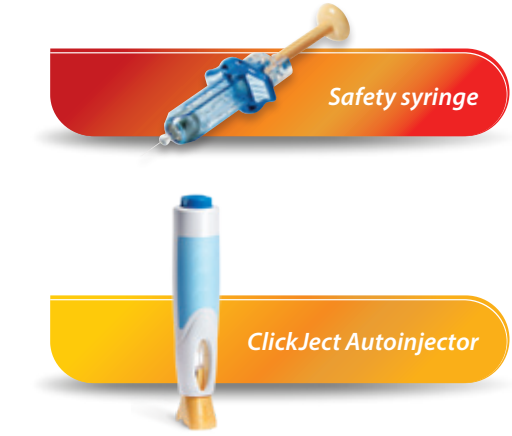
For adult rheumatoid arthritis

ORENCIA is administered as a subcutaneous injection at a weekly dose of 125 mg, regardless of weight, and may be initiated with or without an intravenous loading dose.

If an intravenous loading dose is administered, the first 125 mg subcutaneous injection should be given within 1 day, followed by 125 mg subcutaneous injections once weekly.

Patients switching from ORENCIA intravenous therapy to subcutaneous administration should administer their first subcutaneous dose instead of their next scheduled intravenous dose.

ORENCIA subcutaneous injection can be given using one of the following prefilled devices:



ORENCIA is intended for use under the guidance of a physician or healthcare practitioner. After proper training in subcutaneous injection technique, a patient may self-inject ORENCIA if a physician/healthcare practitioner determines that it is appropriate.

ORENCIA INTRAVENOUS INJECTION DOSING AND ADMINISTRATION

For adult rheumatoid arthritis

ORENCIA should be administered as a 30-minute intravenous infusion at the dose specified in the table. Following the initial administration, ORENCIA should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter.

DOSE OF INTRAVENOUS ORENCIA

Body weight of patient	Dose	Number of vials*
< 60 kg	500 mg	2
60 to 100 kg	750 mg	3
> 100 kg	1000 mg	4

*Each vial provides 250 mg of abatacept for administration.

ORENCIA SUPPORT

For patients prescribed subcutaneous ORENCIA

Self-injection video

Patients can watch an online training video that will take them through each step of self-injecting using the ClickJect Autoinjector or safety syringe.

Sharps container

Patients can order a complimentary sharps container and replacement online.

THE SELF-INJECTION VIDEOS AND SHARPS CONTAINER ORDER FORMS CAN BE ACCESSED ONLINE

bms.com/au/gated/OrenciaGO.html

or scan the QR code

password: BMSGO

For further information regarding ORENCIA, please consult the full Product Information or contact Bristol-Myers Squibb medical information on 1800 067 567 or medinfo.australia@bms.com

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PBS Information: Authority required for the treatment of rheumatoid arthritis. Refer to PBS schedule for full authority information.
This product is not listed on the PBS for the treatment of psoriatic arthritis.

Before prescribing, please review Product Information. Full PI is available from Bristol-Myers Squibb Australia Medical Information, telephone: 1800 067 567.

Minimum Product Information. Indications: 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). **Contraindications:** Patients with known hypersensitivity to ORENCIA or any of its components; patients with severe infections such as sepsis, abscesses, tuberculosis and opportunistic infections. **Precautions:** ORENCIA should not be administered concurrently with other biological DMARDs; hypersensitivity with any injectable protein; infections including screening for tuberculosis and viral hepatitis; infusion-related reactions; malignancies; immunisation; autoimmune processes; blood glucose monitoring; pregnancy (Category C); lactation; paediatrics; elderly; COPD; patients on controlled sodium diet; psoriatic skin lesions. **Adverse Effects:** Upper and lower respiratory tract infection; urinary tract infection; herpes infections; pneumonia; headache; dizziness; hypertension; cough; abdominal pain; diarrhoea; nausea; dyspepsia; mouth ulceration; aphthous stomatitis; rash; fatigue; asthenia; local injection site reactions; abnormal liver function tests; for other adverse effects see full Product Information. **Dosage and Administration:** Intravenous (IV): 30-minute infusion at 0, 2 and 4 weeks, then every 4 weeks thereafter with weight-adjusted dosing: Adults: < 60 kg, 500 mg; 60 to 100 kg, 750 mg; > 100 kg, 1 gram. In paediatric patients: < 75 kg, 10 mg/kg; > 75 kg, dose as per adult regimen, max 1 g. Subcutaneous (SC): weekly dose of 125 mg regardless of weight and may be initiated with or without an IV loading dose. Patients switching from ORENCIA IV to SC should administer the first SC dose instead of the next scheduled monthly IV dose. **References:** ORENCIA® Approved Product Information, December 2019. Arthritis Australia. Arthritis Information Sheet – Blood tests for arthritis. www.arthritisaustralia.com.au/images/stories/documents/info_sheets/2015/Medical%20management/Bloodtestsforarthritis.pdf. Accessed August 2021. ORENCIA® is a registered trade mark of Bristol-Myers Squibb Australia Pty Ltd. ABN 33 004 333 322. Level 2, 4 Nexus Court, Mulgrave VIC 3170. Tel (03) 8523 4200. Fax (03) 8523 4455. Date of preparation: August 2021. 427-AU-2100108. BMRH22365W.

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