



Orencia[®] (abatacept) – Expanded indication

- On March 30, 2017, the **FDA approved** Bristol-Myers Squibb's **Orencia (abatacept)** injection, for reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA).
 - Previously, Orencia was approved for patients ≥ 6 years old with JIA.
 - Orencia may be used as monotherapy or concomitantly with methotrexate.
 - Orencia should not be administered concomitantly with tumor necrosis factor (TNF) antagonists and is not recommended for concomitant use with other biologic rheumatoid arthritis (RA) therapy, such as **Kineret[®] (anakinra)**.
- Orencia is also approved for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. Orencia may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs other than TNF antagonists.
- The approval of Orencia's expanded indication was based on pharmacokinetic exposure and extrapolation of established efficacy of intravenous (IV) Orencia in polyarticular JIA and subcutaneous (SC) Orencia in patients with RA.
 - The safety and immunogenicity of Orencia for SC injection in children 2 – 17 years of age were assessed descriptively.
- For patients with JIA, Orencia may be given as an IV infusion (≥ 6 years old) or a SC injection (≥ 2 years old) based on body weight. IV dosing has not been studied in patients < 6 years old.
 - For IV infusion, following the initial administration, Orencia should be given at 2 and 4 weeks after the initial infusion and every 4 weeks thereafter.
 - The maximum dose per IV infusion should not exceed 1,000 mg.
 - For SC injection, Orencia is administered once weekly. Orencia for SC injection should be initiated without an IV loading dose.
 - The safety and efficacy of Orencia ClickJect[™] autoinjector for SC injection has not been studied in patients < 18 years of age.
- For adult patients with RA, Orencia may be administered as an IV infusion or as a SC injection. Refer to the Orencia drug label for the recommended dose in RA.
- In addition to the 250 mg single-use vial, 125 mg/mL prefilled syringe, and 125 mg/mL ClickJect autoinjector, Orencia will also be available as 50 mg/0.4 mL and 87.5 mg/0.7 mL prefilled syringes for SC use.



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