
your confidence
GROWS
E.Rx
72945
E.Rx
72946
ACTONIB® 2
Baricitinib
28 scored coated tablets
Each tablet contains:
Baricitinib 2 mg
ACTONIB® 4
Baricitinib
14 scored coated tablets
Each tablet contains:
Baricitinib 4 mg
Actonib
Baricitinib S.C.tablets 2, 4 mg

Severe alopecia areata

- 14-25% of patients will progress to alopecia totalis or alopecia universalis
- An association with atopic dermatitis exists in 39% of cases
- The potential for hair regrowth remains since the inflammatory process does not destroy hair follicles, especially stem cell.
- Up to 34-50% of patients may recover spontaneously within one year, although most patients will experience multiple episodes of alopecia.[1]

Actonib

The once daily systemic FDA approved medicine for adults with severe alopecia areata

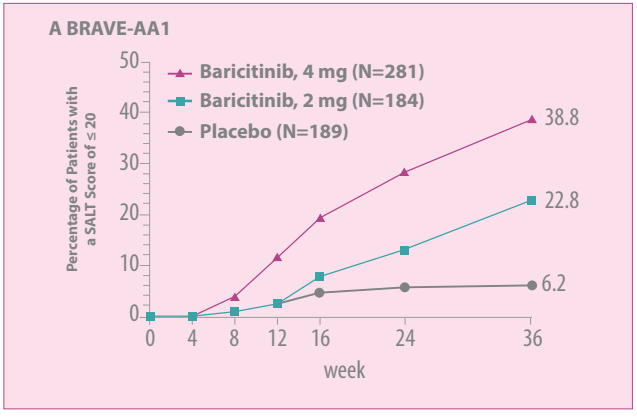
FDA APPROVED

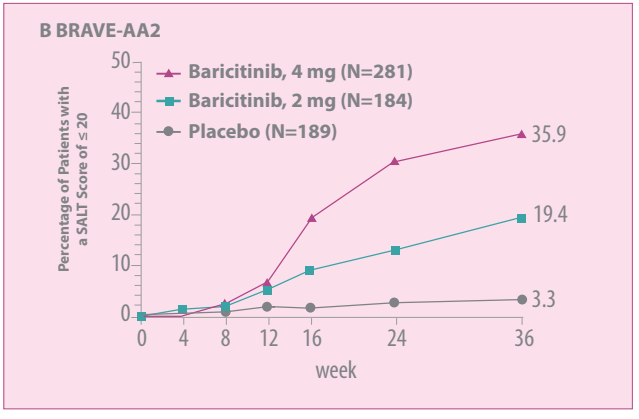
Baricitinib got **FDA approval** on June 23, 2022 based on the results of 02 phase III trial: BRAVE-AA1 and BRAVE-AA2 for treatment of adult patients with severe alopecia areata. [2]

≥90% at 36 weeks

Scalp hair coverage with Baricitinib 4mg once daily

≥80% at 24 weeks





Actonib

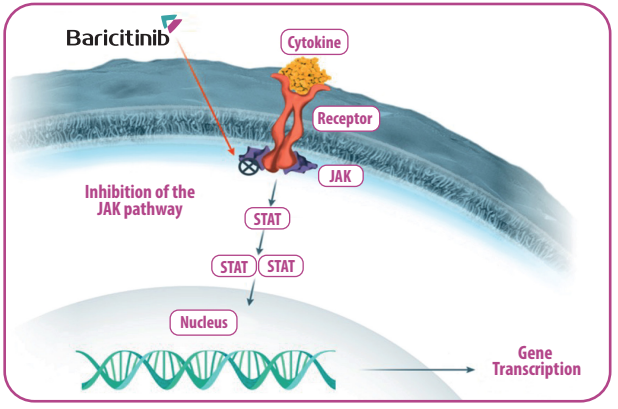
EMA Approved for Treatment of Moderate to Severe Atopic Dermatitis in Adult Patients Who are Candidates for Systemic Therapy [3]

EMA APPROVED

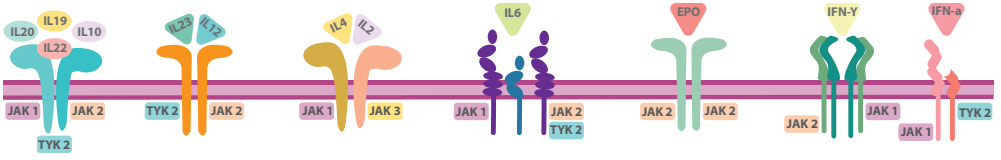
Actonib mechanism of action

Baricitinib is effective for regrewing scalp hair, eyebrows and eyelashes by selective and reversible inhibition of Janus kinase enzymes :

- Reduces inflammation and damage that occur in alopecia areata and atopic dermatitis
- Suppress immune signaling pathway involved in alopecia areata
- Reduces serum IgG, IgM, IgA, and C-reactive protein [4]
- Decreases CD8+ T cell infiltration, and expression of MHC class I and II and return IFN gene expression to normal
- Reducing the phosphorylation and activation of STATs [5]



Actonib Inhibits all cytokine receptors [6]



	IL10 family receptor	Cytokine sharing the IL-12Rβ1	Cytokine receptor sharing the γ-chain	Cytokine receptor sharing the gp130	Homodimeric Cytokine receptor	IFN-γ receptor	IFN-α receptor
✓ JAK1 JAK2 JAK3 Inhibitors: Baricitinib	+	+	+	+	+	+	+
JAK1 JAK3 Inhibitors: Tofacitinib	+	-	+	+	-	+	+

Actonib dosing & administration

Alopecia Areata:

Initial: 2 mg oral once daily; if response is inadequate may increase to 4 mg once daily

For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider initiating therapy with 4 mg once daily

In patients receiving 4 mg once daily (as initial therapy or after a dose increase), reduce dose to 2 mg once daily once an adequate response is achieved

Atopic Dermatitis:

The recommended dose is 4 mg once a day, but this can be reduced to 2 mg, particularly in patients over 75 years old or when the disease is under control. [3]

Notes:

- It is not recommended to discontinue the medication
- Do not initiate in patients with absolute lymphocyte count <500 cells/mm³, absolute neutrophil count <1,000 cells/mm³, or Hb <8 g/dL
- Do not use in combination with other Janus kinase inhibitors, biologic immunomodulators or other potent immunosuppressants [7]

Actonib 2mg, 4mg

Generic Name: Baricitinib **Composition:** (Tablet): 2mg or 4mg Baricitinib. **Dosage Form:** Oral Tablet. **Indication & Dosage:** **Alopecia areata:** Oral: Initial: 2 mg once daily; if response is inadequate may increase to 4 mg once daily. For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider initiating therapy with 4 mg once daily. In patients receiving 4 mg once daily (as initial therapy or after a dose increase), reduce dose to 2 mg once daily once an adequate response is achieved, **COVID-19, hospitalized patients:** Oral: 4 mg once daily, as part of an appropriate combination regimen, for 14 days or until hospital discharge, **Rheumatoid arthritis:** Oral: 2 mg once daily. **Adverse Reactions:** AA/RA: infection, upper respiratory tract infection, COVID 19 treatment: hepatic: increased serum alanine aminotransferase and serum aspartate aminotransferase. **Contraindications:** There are no contraindications listed in the US manufacturer's labeling. Canadian labeling: Additional contraindications (not in US labeling): Hypersensitivity to baricitinib or any component of the formulation. **Warnings/Precautions:** Tuberculosis, Infections, Malignancy and lymphoproliferative disorders, Lipid abnormalities, GI perforations, Hematologic toxicity, Hepatic effects Hypersensitivity. **Pregnancy:** Placental transfer of baricitinib may be expected based on molecular weight (ACR [Sammaritano 2020]). Outcome data following baricitinib exposure in pregnancy are limited (Costanzo 2020; NIH 2022). Recommendations for use of baricitinib in pregnant patients with rheumatic and musculoskeletal diseases are not available due to lack of data. Data collection to monitor pregnancy and infant outcomes following exposure to baricitinib is ongoing. Patients exposed to baricitinib during pregnancy are encouraged to notify the manufacturer. **Breast-Feeding:** It is not known if baricitinib is present in breast milk. Due to the risk of serious adverse events in the breastfeeding infant, breastfeeding is not recommended by the manufacturer during therapy and for 4 days after the last dose of baricitinib. Recommendations for use of baricitinib in breastfeeding patients with rheumatic and musculoskeletal diseases are not available due to lack of data. [6]

References:

1. Kenia Lepe; Patrick M. Zito. Alopecia Areata. NCBI Bookshelf. August 25, 2022. 2.Prashant Mishra, Sharmila Sinha, Sandeep Vihan, Navdeep Dahiya, Biju. Vasudevan.2022. Baricitinib: First Systemic Oral Drug for Alopecia Therapy. 3.https://www.ema.europa.eu/en/medicines/human/EPAR/olumiant.2023. 4. Jingya Zhang, Fei Qi , Jie Dong, Yaqi Tan , Ling Gao, Fang Liu .2022. Application of Baricitinib in Dermatology Jingya Zhang. Journal of Inammation Research. 5. Department of Dermatology, Venereology and Allergology, Clinical Research Center for Hair and SkinScience, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany.2021. Alopecia areata – Current understanding and management. 6. Harrison H. Lee, BS, Eran Gwillim, MD, Kevin R. Patel, MD, Tammy Hua, BA, Supriya Rastogi, MD.2020. Epidemiology of alopecia areata, ophiasis, totalis, and universalis: A systematic review and meta-analysis. Journal of the American Academy Dermatology. 7. UpToDate. 2022. https://www.uptodate.com/contents/baricitinib drug-information.

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