# Safety Summary: Oral JAK Inhibitors Used in Alopecia Areata

*Companion resource for clinical education | US focus | Prescribing information reviewed August 2026*

## Scope

This resource summarizes key safety considerations for FDA-approved oral Janus kinase (JAK) inhibitors used in severe alopecia areata (AA). It is intended for education and does not replace full prescribing information, local protocols or individualized clinical judgment. Product labels should be checked before treatment decisions, as indications and monitoring requirements may change.

## Agents included

| Agent | Kinase selectivity | Current US AA indication (August 2026) | Practical safety differentiator |
|---|---|---|---|
| Baricitinib | JAK1/JAK2 inhibitor | Adults with severe AA | Complete blood count (CBC), hepatic/renal evaluation; lipid assessment at approximately 12 weeks after initiation in AA. |
| Ritlecitinib | JAK3/TEC family kinase inhibitor | Adults and adolescents aged 12 years and older with severe AA | Absolute lymphocyte count (ALC) and platelet count before treatment and at 4 weeks, then according to routine patient management. |
| Deuruxolitinib | JAK1/JAK2 inhibitor | Adults with severe AA | CYP2C9 genotype required; baseline and periodic lipid assessment; CYP2C9 inhibitor restrictions. |

## Class-level boxed warning

**Boxed warning**

- Increased risk of serious bacterial, fungal, viral, and opportunistic infections that may lead to hospitalization or death, including tuberculosis (TB). Interrupt treatment if serious infection occurs until the infection is controlled. JAKi should not be given to patients with active tuberculosis. Test for latent TB before and during therapy; start treating latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test. Monitor all patients for signs and symptoms of infection during and after treatment with JAKi.
- Higher rate of all-cause mortality, including sudden cardiovascular death with JAKi vs. TNF blockers in rheumatoid arthritis (RA) patients.
- Malignancies were reported in patients treated with JAKi. Higher rate of lymphomas and lung cancers with JAKi vs. TNF blockers in RA patients.
- Higher rate of major adverse cardiovascular events (MACE; defined as cardiovascular death, myocardial infarction, and stroke) with JAKi vs. TNF blockers in RA patients.
- Thrombosis has occurred in patients treated with JAKi. Increased incidence of pulmonary embolism, venous and arterial thrombosis with JAKi vs. TNF blockers.

## Main safety domains across the JAKi class

- **Serious infections, including TB and opportunistic infections:** evaluate infection risk and avoid use in active serious infection.
- **Viral reactivation and viral hepatitis:** screen in accordance with label recommendations and clinical guidance.
- **Malignancy, MACE and thrombosis:** individualize risk assessment, especially in patients with cardiovascular risk factors, smoking history, prior malignancy or thrombotic history.
- **Vaccination:** update immunizations before treatment where appropriate; live vaccines should be avoided during or immediately/shortly prior to treatment, depending on the agent label.
- **Laboratory abnormalities:** cytopenias, liver enzyme elevations, lipid changes and creatine phosphokinase (CPK) elevations are relevant safety considerations, but timing and thresholds differ by product.
- **Combination therapy:** labels generally do not recommend use with other JAKi, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

## Common adverse reactions in AA trials

- **Baricitinib:** Upper respiratory tract infections, headache, acne, hyperlipidemia, CPK increase, urinary tract infection, liver enzyme elevations, folliculitis, fatigue, lower respiratory tract infections, nausea, genital *Candida* infections, anemia, neutropenia, abdominal pain, herpes zoster, and weight increase.
- **Ritlecitinib:** Headache, diarrhea, acne, rash, urticaria, folliculitis, pyrexia, atopic dermatitis, dizziness, blood CPK increased, herpes zoster, red blood cell count decreased, and stomatitis
- **Deuruxolitinib:** common adverse reactions (1% or more) include headache, acne, nasopharyngitis, blood CPK increased, hyperlipidemia, fatigue, weight increased, lymphopenia, thrombocytosis, anemia, skin and soft tissue infections, neutropenia, and herpes.

## Additional label-specific warnings and precautions

- **Baricitinib:** Hypersensitivity; gastrointestinal perforations; hypoglycemia in patients with diabetes
- **Ritlecitinib:** Hypersensitivity; hypoglycemia in patients with diabetes
- **Deuruxolitinib:** Increased risk of serious adverse reactions in CYP2C9 poor metabolizers or concomitant use of moderate or strong CYP2C9 inhibitors; gastrointestinal perforations; hypoglycemia in patients with diabetes

## Agent-specific monitoring and safety distinctions

| Safety feature | Baricitinib | Ritlecitinib | Deuruxolitinib |
|---|---|---|---|
| Infection evaluation | Active/latent TB evaluation; viral hepatitis screening in accordance with clinical guidelines. Annual TB screening. | TB evaluation; viral hepatitis screening. Initiation is not recommended with hepatitis B or C. Annual TB screening. | TB evaluation; viral hepatitis screening. Treatment is not recommended with active hepatitis B or C. Annual TB screening. |
| Baseline bloods | CBC with differential. Initiation not recommended if ALC <500 cells/$mm^3$, absolute neutrophil count (ANC) <1000 cells/$mm^3$ or hemoglobin <8 g/dL in AA. Creatinine, alanine aminotransferase (ALT) and aspartate aminotransferase (AST). | CBC with differential. ALC and platelets: Initiation not recommended if ALC <500/$mm^3$ or platelets <100,000/$mm^3$. ALT and AST. | CBC with differential. Treatment not recommended if ALC <500 cells/$mm^3$, ANC <1000 cells/$mm^3$ or hemoglobin <8 g/dL. No ALT/AST monitoring. |
| Laboratory monitoring | Evaluate at baseline and thereafter according to routine patient management; interrupt for specified cytopenias/anemia. ALT and AST according to routine management. | ALC and platelet counts before treatment, at 4 weeks and thereafter according to routine patient management; interrupt or discontinue by thresholds. ALT and AST according to routine management. | CBC with differential prior to and periodically during treatment; interrupt and resume by label thresholds. No ALT/AST monitoring. |
| Lipids | Assess lipid parameters approximately 12 weeks after initiation in AA; manage according to hyperlipidemia guidelines. | No lipid monitoring requirement. | Assess lipid parameters at baseline and periodically during treatment; manage according to hyperlipidemia guidelines. |
| Genotype and drug interactions | Consider renal function and relevant drug-interaction guidance from the label. Not recommended for use in combination with other JAKi, biologic immunomodulators, cyclosporine or other potent immunosuppressants. | CYP3A and CYP1A2 interaction considerations; strong CYP3A inducers are not recommended. | CYP2C9 genotype testing before treatment. Contraindicated in CYP2C9 poor metabolizers and with moderate/strong CYP2C9 inhibitors; avoid strong CYP3A and moderate/strong CYP2C9 inducers. |
| Special populations | AA indication is adults. Not recommended in severe hepatic impairment. Not recommended in severe renal impairment (eGFR <30 mL/min/1.73 $m^2$). May cause fetal harm during pregnancy. Breastfeeding not recommended during use. | Approved for adults and adolescents 12 years and older. Not recommended in severe hepatic impairment (Child Pugh C). Contraindicated in patients with known hypersensitivity to ritlecitinib or any of its excipients. No data in pregnancy. Breastfeeding not recommended during use. | AA indication is adults. Not recommended in severe renal impairment or end-stage renal disease (eGFR <30mL/min). Not recommended in severe hepatic impairment (Child Pugh C). May cause fetal harm during pregnancy. Breastfeeding not recommended during use. |

### Avoid a generic JAK inhibitor checklist

Baseline lipid testing, early CBC timing, CYP2C9 genotype testing and pregnancy testing should not be presented as universal label requirements across all AA JAKi. Some are product-specific label requirements, some are local good practice or patient-specific considerations, and some are not universally required by the AA labels.

## Safety checklist for education

- ☐ Confirm current label, indication, age group and dose for the selected product.
- ☐ Review boxed-warning risk domains: infection, malignancy, MACE and thrombosis, in the context of the individual patient.
- ☐ Evaluate active/latent TB and viral hepatitis as required by the selected label and clinical guidance.
- ☐ Check baseline hematology and any product-specific thresholds before initiation.
- ☐ Apply the product-specific monitoring schedule: CBC timing, lipid timing, hepatic monitoring and any interruption/resumption thresholds.
- ☐ Review vaccinations, including herpes zoster where relevant, and avoid live vaccines as directed by the label.
- ☐ Review comorbidities, renal/hepatic function, diabetes, smoking history, prior malignancy, thrombotic history and concomitant medicines.

## Key sources

Baricitinib. Prescribing Information. Eli Lilly and Company. Revised June 2026.

Ritlecitinib. Prescribing Information. Pfizer. Revised June 2026.
Deuruxolitinib. Prescribing Information. Sun Pharmaceutical Industries, Inc. Revised June 2026.
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