Abrocitinib

We **recommend** abrocitinib in AE patients, who are candidates for systemic treatment.	↑↑	**100%** Evidence and consensus based, see Evidence Report

abrocitinib: in licence for ≥ 12 years of age;
dosage ≥ 12 years: 100 or 200 mg per day based on disease burden and risk factors;
dosage adults age ≥ 65: 100 mg per day

Certainty of evidence: Network meta-analysis from 2024[1, 2]:

Short term (up to 16 weeks) vs placebo (NMA medications used in clinical practice)

100 mg
⊕⊕⊕⊕ HIGH for mean difference **EASI** -8.5 (-10.3, -6.7); **POEM** -5.1 (-6.1, -4.1)
⊕⊕⊕◯ MODERATE for mean difference **peak pruritus NRS** -1.6 (-2.1, -1.1); **DLQI** -3.4 (-4.3, -2.6)

200 mg
⊕⊕⊕⊕ HIGH for mean difference **EASI** -12.8 (-14.6, -11.1); **POEM** -8.4 (-9.3, -7.5); **DLQI** -5.6 (-6.3, -4.8)
⊕⊕⊕◯ MODERATE for mean difference **peak pruritus NRS** -2.4 (-3, -1.8)

For abrocitinib versus other drugs, see Evidence Report

Mechanisms of action and efficacy

Abrocitinib is an oral JAK1 selective inhibitor, approved from the age of 12, that has shown efficacy in patients with moderate-to-severe AE when used as a monotherapy (MONO-1 and -2 studies) and in combination with topical therapies in achieving treatment response in comparison to placebo (COMPARE study), as measured using IGA and EASI-75 response. For instance, the proportion of patients with EASI-75 response at week 12 was significantly higher with abrocitinib 100 mg (~40-45%) and abrocitinib 200 mg (~61-63%) compared to placebo (~10-12%) in the MONO studies. In the COMPARE study the proportion of patients with EASI-75 response was significantly higher with abrocitinib 100 mg (~59%) and abrocitinib 200 mg (~70%) compared to placebo (27%).[3] Similar efficacy has been demonstrated in the adolescent JADE TEEN trial for both the 100mg and 200mg doses, in combination with topical therapies.[4] Importantly, in the COMPARE study (which had dupilumab as a comparator arm) higher responder rates were observed with abrocitinib 200 mg compared to dupilumab (p-values not calculated) after 16 weeks of treatment. The efficacy of abrocitinib 100 mg and dupilumab was similar in this subgroup. The results indicate that abrocitinib 200 mg may provide a higher probability of treatment response compared to dupilumab in patients with severe AE.[5]

Dosage: acute flare, short term, long term

Abrocitinib is licenced at the 100 mg and the 200 mg daily doses, with the lower dose recommended for adolscents as a starting dose. Starting with the higher dose usually leads to a faster clinical response, better drug survival and adherence, and may therefore be advisable in younger adults and in otherwise healthy patients. One study assessed flare prevention, i.e. the risk and probability of flares and recapture of treatment response following a flare. Of 1233 patients, 798 responders to induction with abrocitinib 200 mg (64.7%) were randomly assigned to dose maintenance, dose reduction or treatment withdrawal (placebo). The flare probability during maintenance was 18.9%, 42.6%, and

80.9% with abrocitinib 200 mg, abrocitinib 100 mg, and placebo, respectively by week 52. Among patients with flare in the abrocitinib 200 mg, abrocitinib 100 mg, and placebo groups, 36.6%, 58.8%, and 81.6% regained IGA 0/1 response, respectively, and 55.0%, 74.5%, and 91.8% regained EASI index response, respectively, with rescue treatment of abrocitinib 200 mg plus medicated topical therapy.[6]

Safety

Based on long-term follow up of patients from the phase II and III trials as well as one long-term extension study, with a total n of 2856 (1614 patient-years (PY); total exposure in the all-abrocitinib cohort was ≥ 24 weeks in 1248 patients and ≥ 48 weeks in 606 (maximum 108 weeks). In the placebo-controlled cohort (n = 1540), dose-related adverse events (200 mg, 100 mg, placebo) were nausea (14.6%, 6.1%, 2.0%), headache (7.8%, 5.9%, 3.5%), and acne (4.7%, 1.6%, 0%). Platelet count was reduced transiently in a dose-dependent manner; 2/2718 patients (200-mg group) had confirmed platelet counts of $< 50 \times 10^3/mm^3$ at week 4. Incidence rates (IRs) were 2.33/100PY and 2.65/100 PY for serious infection, 4.34/100PY and 2.04/100PY for herpes zoster, and 11.83/100PY and 8.73/100PY for herpes simplex in the 200-mg and 100-mg groups, respectively.[7]

Screening and monitoring

For baseline screening, the manufacturer's label laboratory monitoring recommendations are full blood count including platelet count, absolute lymphocyte count (ALC), absolute neutrophil count (ANC), and haemoglobin (Hb) as well as lipid parameters. Infection screening for HIV, hepatitis B and C as well as TB is advisable before initiation of therapy.

In practice, the guideline group considers the same baseline screening and treatment monitoring investigations applicable to all JAK-Inhibitors. For baseline screening this is a full blood count, renal, liver and lipid profile and hepatitis B and C, HIV and TB screen.

For follow up monitoring we propose a full blood count, renal, liver and lipid profile at four weeks into treatment and then three-monthly while on therapy. The guideline group does not advocate for mandatory monitoring of creatinine phosphokinase levels in asymptomatic patients.

Combination with other treatments

We recommend combining abrocitinib, as any systemic treatment, with emollients and, whenever needed, topical anti-inflammatory treatment in AE patients

Special considerations

Abrocitinib is a new JAK-Inhibitor and has not been formally tested in other inflammatory diseases. Please refer to the special considerations in the JAK-Inhibitor introduction chapter.

References

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