

TREATMENT MANAGEMENT - BARICITINIB



WHEN SHOULD I REDUCE THE DOSE? (see relevant section 6.5 in BARI-protocol)

Renal impairment

- eGFR ≥ 30 to < 60 mL/min/1.73 m² \Rightarrow 2 mg once daily
- eGFR ≥ 15 to < 30 mL/min/1.73 m²
 \Rightarrow **withdraw** treatment **or** 2 mg every other day: according to PI opinion
- eGFR < 15 mL/min/1.73 m² or on dialysis \Rightarrow **withdraw** treatment

Drug interactions

- Simultaneous use of benzylpenicillin (penicillin-G) or probenecid
 \Rightarrow Reduce to 2 mg once daily



WHEN SHOULD I DISCONTINUE BARICITINIB TEMPORARILY? (see relevant section 7.1 in BARI-protocol)

Laboratory abnormality

- *ANC < 1000 cells/ μ L **or**
- *ALC < 200 cells/ μ L **or**
- Hb < 8.0 g/dL **or**
- AST **and/or** ALT > 5 times ULN


*on 1 sample



WHEN SHOULD I DISCONTINUE BARICITINIB PERMANENTLY? (see relevant section 7.1 in BARI-protocol)

Laboratory abnormality

- WBC count < 1000 cells/ μ L **or**
- ANC < 500 cells/ μ L **or**
- ALC < 200 cells/ μ L **or**
- AST **or** ALT > 8 x ULN **or**
- AST **or** ALT > 3 x ULN **and** total bilirubin > 2 x ULN **or** INR > 1.5

- Prohibited medication started (see exclusion criteria)
 **Exception: tocilizumab as rescue therapy according to the current version of the protocol**
- Pregnancy (see relevant section 10.1)
- Systemic hypersensitivity reaction
- New malignancy
- HIV infection (detectable HIV-RNA and/or AIDS)
- Tuberculosis (active or latent)
- Active hepatitis B (HBV-DNA) or C infection (HCV-RNA)
- VTE (DVT/PE)
- Serious infection not responding to standard therapy
- Diverticulitis (including exacerbation of pre-existing diverticular disease)

*on 2 samples: 48 h to 7 days apart

Acronyms

ANC : Absolute Neutrophil Count
ALC : Absolute Lymphocyte Count
ALT : Alanine aminotransferase
AST : Aspartate aminotransferase

DVT : Deep Vein Thrombosis
eGFR : estimated Glomerular Filtration Rate
Hb : Haemoglobin
HIV : Human Immunodeficiency Virus

PE : Pulmonary Embolism
ULN : Upper limit of normal
VTE : Venous ThromboEmbolism