

- **CONCEPTION AND CONTRACEPTION** Effective contraception required during treatment and for up to 3 months after last dose.
  - **PREGNANCY** Manufacturer advises avoid unless potential benefit outweighs risk.
  - **BREAST FEEDING** Consider if benefit outweighs risk—no known if present in human milk.
  - **RENAL IMPAIRMENT** Limited information available but manufacturer advises no dose adjustment required.
  - **PRE-TREATMENT SCREENING** Patients should be evaluated for latent and active tuberculosis before starting treatment.
  - **MONITORING REQUIREMENTS**
    - ▶ Manufacturer advises monitor full blood count including neutrophil count before starting treatment, 1–2 months after starting treatment, and periodically thereafter.
    - ▶ Manufacturer advises monitor for signs and symptoms of infection (including tuberculosis) during and after treatment.
  - **HANDLING AND STORAGE** Manufacturer advises store in a refrigerator (2–8 °C).
  - **PATIENT AND CARER ADVICE** Manufacturer advises patients and carers should be instructed to seek medical advice if signs or symptoms suggestive of tuberculosis (including persistent cough, weight loss and subfebrile temperature) occur.
- Driving and skilled tasks** Manufacturer advises patients and carers should be counselled on the effects on driving and performance of skilled tasks—increased risk of dizziness and drowsiness.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

#### Solution for injection

- ▶ **Ilaris** (Novartis Pharmaceuticals UK Ltd)  
**Canakinumab 150 mg per 1 ml** Ilaris 150mg/1ml solution for injection vials | 1 vial [PoM] £9,927.80

## IMMUNOSUPPRESSANTS > MONOCLONAL ANTIBODIES > ANTI-LYMPHOCYTE

### Basiliximab

16-Nov-2017

- **DRUG ACTION** Basiliximab is a monoclonal antibody that acts as an interleukin-2 receptor antagonist and prevents T-lymphocyte proliferation.

#### ● INDICATIONS AND DOSE

**Prophylaxis of acute rejection in allogeneic renal transplantation used in combination with ciclosporin and corticosteroid-containing immunosuppression regimens (specialist use only)**

- ▶ BY INTRAVENOUS INJECTION, OR BY INTRAVENOUS INFUSION
- ▶ Child 1–17 years (body-weight up to 35 kg): Initially 10 mg, dose to be administered within 2 hours before transplant surgery, followed by 10 mg after 4 days, dose administered after transplant surgery, withhold second dose if severe hypersensitivity or graft loss occurs
- ▶ Child 1–17 years (body-weight 35 kg and above): Initially 20 mg, administered within 2 hours before transplant surgery, followed by 20 mg after 4 days, dose to be administered after surgery, withhold second dose if severe hypersensitivity or graft loss occurs

- **CAUTIONS** Off-label use in cardiac transplantation—increased risk of serious cardiac side-effects
- **INTERACTIONS** → Appendix 1: monoclonal antibodies
- **SIDE-EFFECTS** Capillary leak syndrome · constipation · cytokine release syndrome · dyspnoea · fever · heart failure · hypersensitivity · hypertension · hypertrichosis · hypotension · increased risk of infection · myocardial

infarction · pulmonary oedema · respiratory disorders · sepsis · skin reactions · sneezing · tachycardia

- **CONCEPTION AND CONTRACEPTION** Adequate contraception must be used during treatment and for 16 weeks after last dose.
- **PREGNANCY** Manufacturer advises avoid—no information available.
- **BREAST FEEDING** Manufacturer advises avoid—no information available.
- **DIRECTIONS FOR ADMINISTRATION** For *intravenous infusion*, dilute reconstituted solution to a concentration not exceeding 400 micrograms/mL, with Glucose 5% or Sodium Chloride 0.9%; give over 20–30 minutes.

#### ● NATIONAL FUNDING/ACCESS DECISIONS

##### NICE decisions

- ▶ **Immunosuppressive therapy for kidney transplant in children and young people (October 2017)** NICE TA482  
**Basiliximab**, when used as part of an immunosuppressive regimen that includes a calcineurin inhibitor, is recommended as an initial option to prevent organ rejection in patients having a kidney transplant. The use of basiliximab with tacrolimus is outside the terms of the marketing authorisation. If this combination is prescribed, the prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented.  
 Patients whose treatment was started within the NHS before this guidance was published should have the option to continue treatment, without change to their funding arrangements, until they and their NHS clinician consider it appropriate to stop. [www.nice.org.uk/guidance/TA482](http://www.nice.org.uk/guidance/TA482)

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

#### Powder and solvent for solution for injection

- ▶ **Simulect** (Novartis Pharmaceuticals UK Ltd)  
**Basiliximab 10 mg** Simulect 10mg powder and solvent for solution for injection vials | 1 vial [PoM] £758.69 (Hospital only)  
**Basiliximab 20 mg** Simulect 20mg powder and solvent for solution for injection vials | 1 vial [PoM] £842.38 (Hospital only)

## IMMUNOSUPPRESSANTS > PURINE SYNTHESIS INHIBITORS

### Mycophenolate mofetil

09-Mar-2018

#### ● INDICATIONS AND DOSE

**Prophylaxis of acute rejection in renal transplantation (in combination with a corticosteroid and ciclosporin) (under expert supervision)**

- ▶ BY MOUTH
- ▶ Child: 600 mg/m<sup>2</sup> twice daily, consult local protocol for details; maximum 2 g per day

**Prophylaxis of acute rejection in renal transplantation (in combination with a corticosteroid and tacrolimus) (under expert supervision)**

- ▶ BY MOUTH
- ▶ Child: 300 mg/m<sup>2</sup> twice daily, consult local protocol for details; maximum 2 g per day

**Prophylaxis of acute rejection in hepatic transplantation (in combination with a corticosteroid and ciclosporin or tacrolimus) (under expert supervision)**

- ▶ BY MOUTH
- ▶ Child: 10 mg/kg twice daily, increased to 20 mg/kg twice daily, consult local protocol for details; maximum 2 g per day

- **UNLICENSED USE** Not licensed for use in children under 2 years for the prophylaxis of acute rejection in renal