

- **CONCEPTION AND CONTRACEPTION** Manufacturer advises effective contraception required during treatment and for 3 weeks after last dose.
- **PREGNANCY** Avoid—limited information available.
- **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in moderate to severe alcoholic hepatitis.
- **PRE-TREATMENT SCREENING** Tuberculosis Patients should be evaluated for tuberculosis before treatment.
- **MONITORING REQUIREMENTS** Monitor for skin cancer before and during treatment, particularly in those at risk (including patients with psoriasis or a history of PUVA treatment).
- **PRESCRIBING AND DISPENSING INFORMATION** Etanercept is a biological medicine. Biological medicines must be prescribed and dispensed by brand name, see *Biological medicines* and *Biosimilar medicines*, under Guidance on prescribing p. 1.

BENEPALI® SOLUTION FOR INJECTION Manufacturer advises patients requiring less than the full 50 mg dose should **not** receive *Benepali*®—if an alternate dose is required, other etanercept formulations providing this option should be used.

- **PATIENT AND CARER ADVICE**
Blood disorders Patients and their carers should be advised to seek medical attention if symptoms suggestive of blood disorders (such as fever, sore throat, bruising, or bleeding) develop.
Tuberculosis Patients and their carers should be advised to seek medical attention if symptoms suggestive of tuberculosis (e.g. persistent cough, weight loss, and fever) develop.
Alert card An alert card should be provided.
Medicines for Children leaflet: Etanercept for juvenile idiopathic arthritis www.medicinesforchildren.org.uk/etanercept-juvenile-idiopathic-arthritis

- **NATIONAL FUNDING/ACCESS DECISIONS**
NICE decisions

- ▶ **Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis (December 2015)**
NICE TA373

- Etanercept is recommended as an option for treating:
- polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA, in patients 2 years and over whose disease has responded inadequately to, or who are intolerant of, methotrexate;
 - enthesitis-related JIA in patients 12 years and over whose disease has responded inadequately to, or who are intolerant of, conventional therapy;
 - psoriatic JIA in patients 12 years and over whose disease has responded inadequately to, or who are intolerant of, methotrexate.

www.nice.org.uk/guidance/ta373

- ▶ **Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people (July 2017)**

- Etanercept is recommended as an option for treating plaque psoriasis in children and young people aged 6 years and older, only if the disease:
- is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more, and
 - has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contra-indicated or not tolerated.

If the psoriasis has not responded adequately, stop treatment at 12 weeks. An adequate response is defined as a 75% reduction in PASI score from the start of treatment.

Patients currently receiving etanercept who do not meet the above criteria and whose treatment was started within the NHS before this guidance was published, should have the option to continue treatment until they and their clinician consider it appropriate to stop.

www.nice.org.uk/guidance/TA455

- **Scottish Medicines Consortium (SMC) decisions**

The *Scottish Medicines Consortium* has advised (February 2013) that etanercept (*Enbrel*®) is accepted for restricted use within NHS Scotland for the treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to or are intolerant of methotrexate, psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to or are intolerant of conventional therapy. It is restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology).

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

- **Solution for injection**

CAUTIONARY AND ADVISORY LABELS 10

- ▶ **Benepali** (Biogen Idec Ltd) ▼

Etanercept 50 mg per 1 ml Benepali 50mg/1ml solution for injection pre-filled pens | 4 pre-filled disposable injection [PoM] £656.00 DT = £715.00

Benepali 50mg/1ml solution for injection pre-filled syringes | 4 pre-filled disposable injection [PoM] £656.00 DT = £715.00

- ▶ **Enbrel** (Pfizer Ltd)

Etanercept 50 mg per 1 ml Enbrel 50mg/1ml solution for injection pre-filled syringes | 4 pre-filled disposable injection [PoM] £715.00 DT = £715.00 (Hospital only)

Enbrel 25mg/0.5ml solution for injection pre-filled syringes | 4 pre-filled disposable injection [PoM] £357.50 DT = £357.50 (Hospital only)

- ▶ **Enbrel MyClic** (Pfizer Ltd)

Etanercept 50 mg per 1 ml Enbrel 25mg/0.5ml solution for injection pre-filled MyClic pens | 4 pre-filled disposable injection [PoM] £357.50 (Hospital only)

Enbrel 50mg/1ml solution for injection pre-filled MyClic pens | 4 pre-filled disposable injection [PoM] £715.00 DT = £715.00 (Hospital only)

- **Powder and solvent for solution for injection**

CAUTIONARY AND ADVISORY LABELS 10

EXCIPIENTS: May contain Benzyl alcohol

- ▶ **Enbrel** (Pfizer Ltd)

Etanercept 10 mg Enbrel Paediatric 10mg powder and solvent for solution for injection vials | 4 vial [PoM] £143.00 (Hospital only)

Etanercept 25 mg Enbrel 25mg powder and solvent for solution for injection vials | 4 vial [PoM] £357.50 (Hospital only)

Golimumab

03-Aug-2018

- **INDICATIONS AND DOSE**

- **Polyarticular juvenile idiopathic arthritis (initiated by a specialist)**

- ▶ **BY SUBCUTANEOUS INJECTION**

- ▶ Child (body-weight 40 kg and above): 50 mg once a month, on the same date each month, review treatment if no response after 3–4 doses

- **CONTRA-INDICATIONS** Moderate or severe heart failure · severe active infection

- **CAUTIONS** Active infection (do not initiate until active infections are controlled; discontinue if new serious infection develops until infection controlled) · children should be brought up to date with current immunisation schedule before initiating therapy · demyelinating disorders (risk of exacerbation) · hepatitis B virus—monitor for active infection · history or development of malignancy · mild heart failure (discontinue if symptoms develop or worsen) · predisposition to infection · risk factors for