

45 mg every 12 weeks, consider discontinuation if no response within 28 weeks

- ▶ Child 12–17 years (body-weight 100 kg and above): Initially 90 mg, then 90 mg after 4 weeks, then 90 mg every 12 weeks, consider discontinuation if no response within 28 weeks

- **CONTRA-INDICATIONS** Active infection
- **CAUTIONS** Development of malignancy · history of malignancy · predisposition to infection · start appropriate treatment if widespread erythema and skin exfoliation develop, and stop ustekinumab treatment if exfoliative dermatitis suspected

#### CAUTIONS, FURTHER INFORMATION

- ▶ **Tuberculosis** Active tuberculosis should be treated with standard treatment for at least 2 months before starting ustekinumab. Patients who have previously received adequate treatment for tuberculosis can start ustekinumab but should be monitored every 3 months for possible recurrence. In patients without active tuberculosis but who were previously not treated adequately, chemoprophylaxis should ideally be completed before starting ustekinumab. In patients at high risk of tuberculosis who cannot be assessed by tuberculin skin test, chemoprophylaxis can be given concurrently with ustekinumab.

- **INTERACTIONS** → Appendix 1: monoclonal antibodies

#### ● SIDE-EFFECTS

- ▶ **Common or very common** Arthralgia · asthenia · back pain · diarrhoea · dizziness · headache · increased risk of infection · myalgia · nausea · oropharyngeal pain · skin reactions · vomiting
- ▶ **Uncommon** Depression · facial paralysis · hypersensitivity (may be delayed) · nasal congestion
- ▶ **Rare or very rare** Respiratory disorders
- ▶ **Frequency not known** Increased risk of cancer

- **CONCEPTION AND CONTRACEPTION** Manufacturer advises effective contraception during treatment and for 15 weeks after stopping treatment.

- **PREGNANCY** Avoid.

- **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.

#### ● PRE-TREATMENT SCREENING

- Tuberculosis Patients should be evaluated for tuberculosis before treatment.

#### ● MONITORING REQUIREMENTS

- ▶ Monitor for non-melanoma skin cancer, especially in patients with a history of PUVA treatment or prolonged immunosuppressant therapy, or those over 60 years of age.
- ▶ Monitor for signs and symptoms of exfoliative dermatitis or erythrodermic psoriasis.

#### ● PATIENT AND CARER ADVICE

- Exfoliative dermatitis Patients should be advised to seek prompt medical attention if symptoms suggestive of exfoliative dermatitis or erythrodermic psoriasis (such as increased redness and shedding of skin over a larger area of the body) develop.
- Tuberculosis Patients should be advised to seek medical attention if symptoms suggestive of tuberculosis (e.g. persistent cough, weight loss, and fever) develop.

#### ● NATIONAL FUNDING/ACCESS DECISIONS

##### NICE decisions

- ▶ Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people (July 2017) NICE TA455 Ustekinumab is recommended as an option for treating plaque psoriasis in children and young people aged 12 years or older, only if the disease:
  - is severe, as defined by a total 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 16 weeks. An adequate response is defined as a 75% reduction in PASI score from the start of treatment.

Patients currently receiving ustekinumab 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](http://www.nice.org.uk/guidance/ta455)

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

#### Solution for injection

CAUTIONARY AND ADVISORY LABELS 10

- ▶ **Stelara** (Janssen-Cilag Ltd)

**Ustekinumab 90 mg per 1 ml** Stelara 90mg/1ml solution for injection pre-filled syringes | 1 pre-filled disposable injection (PoM) £2,147.00 (Hospital only)

Stelara 45mg/0.5ml solution for injection vials | 1 vial (PoM) £2,147.00 (Hospital only)

Stelara 45mg/0.5ml solution for injection pre-filled syringes | 1 pre-filled disposable injection (PoM) £2,147.00 (Hospital only)

## RETINOID AND RELATED DRUGS

### Acitretin

28-Jan-2020

- **DRUG ACTION** Acitretin is a metabolite of etretinate.

#### ● INDICATIONS AND DOSE

**Severe extensive psoriasis resistant to other forms of therapy (under expert supervision) | Palmoplantar pustular psoriasis (under expert supervision) | Severe congenital ichthyosis (under expert supervision)**

##### ▶ BY MOUTH

- ▶ Child 1 month–11 years: 0.5 mg/kg once daily; increased if necessary to 1 mg/kg once daily, to be taken with food or milk, careful monitoring of musculoskeletal development required; maximum 35 mg per day
- ▶ Child 12–17 years: Initially 25–30 mg daily for 2–4 weeks, then adjusted according to response to 25–50 mg daily, increased to up to 75 mg daily, dose only increased to 75 mg daily for short periods in psoriasis

**Severe Darier's disease (keratosis follicularis) (under expert supervision)**

##### ▶ BY MOUTH

- ▶ Child 1 month–11 years: 0.5 mg/kg once daily; increased if necessary to 1 mg/kg once daily, to be taken with food or milk, careful monitoring of musculoskeletal development required; maximum 35 mg per day
- ▶ Child 12–17 years: Initially 10 mg daily for 2–4 weeks, then adjusted according to response to 25–50 mg daily

**Harlequin ichthyosis (under expert supervision)**

##### ▶ BY MOUTH

- ▶ Neonate: 0.5 mg/kg once daily; increased if necessary to 1 mg/kg once daily, to be taken with food or milk, careful monitoring of musculoskeletal development required.

#### IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE: ORAL RETINOID MEDICINES: REVISED AND SIMPLIFIED PREGNANCY PREVENTION EDUCATIONAL MATERIALS FOR HEALTHCARE PROFESSIONALS AND WOMEN (JUNE 2019)

New prescriber checklists, patient reminder cards, and pharmacy checklists are available to support the Pregnancy Prevention Programme in women and girls of childbearing potential taking oral acitretin, alitretin, or isotretinoin. Healthcare professionals are reminded