Ustekinumab

Instructions for use

Table 1: Instructions for use (Ustekinumab)

Pre-treatment

- Physicians are encouraged to enroll their patients in a registry (if available)
- Objective assessment of the disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI, Skindex-29 or 17)
- Medical history and physical examination including prior exposure to treatments, malignancies, infections
- Recommended measures include:
    - Check for skin cancer
    - Check for lymphadenopathy
    - Laboratory parameters (see **Table 2**)
    - Exclusion of tuberculosis (see chapter: " tuberculosis")
    - Check for evidence of active infection
    - Check need for vaccines
- Reliable contraception

During treatment

- Objective assessment of the disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI, Skindex-29 or 17)
- Laboratory parameters (see **Table 2**)
- Medical history and physical examination including infections, including monitoring signs and symptoms of tuberculosis
- Reliable contraception

Post-treatment

- After discontinuation of ustekinumab, patients should be followed up with medical history and physical examination
- For information regarding the ongoing need for contraception immediately following biologic treatment cessation, please see chapter "wish for child / pregnancy"

[1] due to personal-financial conflict of interest 4 abstentions

Recommendations for lab controls

Table 2: Recommended laboratory controls (Ustekinumab)

	Period in weeks/months	
Parameter	**Pre-treatment**	**Thereafter, every 3-6 months**
Full Blood count	x	x
Liver enzymes	x	x
Serum creatinine	x	
Urine status	x	
Pregnancy test (urine or blood)	x	
CRP	x	
HBV/HCV	x	
HIV	x	
Interferon gamma release assay (TB exclusion)	x	
Not all tests may be necessary for all patients. Patient history, risk exposure and patient characteristics must be considered. Further specific testing may be required according to clinical signs, risk, and exposure.		
The recommendations are based on clinical experience. No evidence is available.		

Adverse drug reactions

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Infections

Placebo-controlled studies of patients with psoriasis or psoriatic arthritis demonstrate a similar incidence of infections including serious infections between ustekinumab-treated and placebo-treated

patients with no relationship between incidence of infections and dose of ustekinumab received. No patient with latent tuberculosis who received antibiotic prophylaxis prior to ustekinumab treatment developed tuberculosis.

Special consideration during treatment

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Surgery

No recommendation exists in the SmPC regarding surgery in patients treated with ustekinumab. In case of major surgery with high risk of infectious complications, it seems prudent to withhold ustekinumab treatment 15 weeks before surgical intervention. Re-start treatment following surgery if wound healing is satisfactory and there is no evidence of infection.

Important contraindications

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Absolute contraindications:

- Clinically important active infections

Relative contraindications:

- Acute, recurrent or chronic infections
- Pregnancy or breastfeeding
- Previous history of malignancies

Drug interactions

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

As IL-12 and IL-23 do not alter CYP 450 enzymes in vitro, no relevant interactions with drugs are expected with ustekinumab [1].

Overdose/measures in case of overdose

Single doses of up to 6 mg/kg have been administered in clinical studies with no apparent toxicity.

References

1. Cerrone M, Wang X, Neary M, et al. Pharmacokinetics of Efavirenz 400 mg Once Daily Coadministered With Isoniazid and Rifampicin in Human Immunodeficiency Virus-Infected Individuals. *Clin Infect Dis*. Jan 18 2019;68(3):446-452. doi:https://dx.doi.org/10.1093/cid/ciy491