Tildrakizumab

Instructions for use

Table 1: Instructions for use (Tildrakizumab)

Pre-treatment

100 % Agreement [1]

- 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 tildrakizumab, 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 (Tildrakizumab)

	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:

During the placebo controlled phase of clinical studies, all types of infections were low and equal to placebo [1] as well as exposure-adjusted incidence rates of severe infections, malignancies, confirmed extended MACEs, and hypersensitivity reactions over 148 weeks [2].

Special consideration during treatment

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

Surgery

Due to the specific mechanism of action of tildrakizumab, IL23p19 inhibition, the probability of wound healing disorders occurring is low. Patients undergoing surgery should be closely screened for infections and it is recommended to schedule operations so that they do not fall within the period of the next tildrakizumab dose.

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/Breastfeeding

Drug interactions

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

Tildrakizumab is cleared by general protein catabolism processes with no contribution of cytochrome P450 enzymes, and it is not eliminated by renal or hepatic pathways. Therefore, tildrakizumab does not affect the pharmacokinetics of concomitant medications metabolised by CYP enzyme. [3]

Overdose

Doses up to 10 mg/kg intravenously have been safely administered in clinical trials.[3]

References

1. Swiss Specialist Information Ilumetri. 2018. www.swissmedicinfo.ch
2. Reich K, Warren RB, Iversen L, et al. Long-term efficacy and safety of tildrakizumab for moderate-to-severe psoriasis: pooled analyses of two randomized phase III clinical trials (reSURFACE 1 and reSURFACE 2) through 148 weeks. *The British journal of dermatology*. Jun 19 2019;doi:10.1111/bjd.18232
3. European Medicines Agency. IlumetriTM (Tildrakizumab) Summary of product characteristics. Accessed September 2019, https://www.ema.europa.eu/documents/product-information/ilumetri-epar-product-information_en.pdf