Risankizumab

Instructions for use

Table 1: Instructions for use (Risankizumab)

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 risankizumab, 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 (Risankizumab) [1]

	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 additional evidence available.		

Adverse drug reactions

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

Most commonly reported adverse drug reactions were upper respiratory tract infections, including nasopharyngitis, rhinitis, pharyngitis, sinusitis, and tonsillitis.

Injection-site reactions include erythema, pain, pruritus, reaction, swelling, hematoma and haemorrhage.

A recent study [2] using the FDA adverse reporting database (FAERS) suggested a potential signal between use of risankizumab and reports of cerebrovascular accident (CVA). However, this finding was not consistent across the p19 class, and whilst the authors explored the potential confounding effect of the underlying disease (psoriasis) associated risk of CVA, long-term observational data will be necessary to establish whether or not this association is real, and if so, the causal relationship between the two.

Special consideration during treatment

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

Surgery

There is only limited data available on the management of surgery in patients receiving anti-IL-23 treatment. The decision of interrupting risankizumab treatment prior to surgery must be based on individual factors, such as type and risk of surgical procedure, patient characteristics, individual infection risk etc. In case of continuing treatment, the procedure is best placed between two doses.

Important contraindications

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects: [1]

Absolute contraindications:

- Clinically important active infections

Relative contraindications:

- Acute, recurrent or chronic infections
- Pregnancy or breastfeeding

Drug interactions

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

Combination therapy with immunosuppressants, including biologics, or phototherapy have not been evaluated. [1, 3]

Overdose/ measures in case of overdose

In the event of overdose, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment be instituted immediately [1].

References

1. European Medicines Agency. Skyrizi - EMEA/H/C/004759 - IA/0006. Accessed September 2019, https://www.ema.europa.eu/en/medicines/human/EPAR/skyrizi#product-information-section

2. Woods RH. Potential cerebrovascular accident signal for risankizumab: A disproportionality analysis of the FDA Adverse Event Reporting System (FAERS). *British journal of clinical pharmacology*. Nov 2 2022;doi:10.1111/bcp.15581

3. Khatri A, Cheng L, Camez A, Ignatenko S, Pang Y, Othman AA. Lack of Effect of 12-Week Treatment with Risankizumab on the Pharmacokinetics of Cytochrome P450 Probe Substrates in Patients with Moderate to Severe Chronic Plaque Psoriasis. *Clinical pharmacokinetics*. Jun 2019;58(6):805-814. doi:10.1007/s40262-018-0730-x