

Safety of Interleukin-23 Inhibitor: A Pharmacovigilance Study From 2014 to 2022 Based on FAERS

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Abstract

Background: Interleukin-23 (IL-23) inhibitors are widely used in clinical practice for Psoriasis , but multiple adverse events (AEs) have been reported. We aimed to describe the distribution of AEs related IL-23 inhibitors including Guselkumab, Tildrakizumab, Risankizumab, Ustekinumab. Methods: Data from January 1, 2014, to September 30, 2022 were extracted from the FDA Adverse Event Reporting System (FAERS). Disproportionality analysis including reporting odds ratio (ROR) and information component (IC) was performed to access potential signals. It was defined a signal when the lower limit of 95% confidence interval (CI) of ROR (ROR025) more than one or IC(IC025) exceeding zero, with the number of cases greater than or equal to three at the same time. Results: A total of 41,408,408 drug-AE reports were extracted from the FAERS database involving 13271168 people. 704, 13164, 62853, 11399 patients have used Tildrakizumab, Guselkumab, Ustekinumab, Risankizumab and 8, 20, 107 and 115 signals were found respectively. The “infections and infestations” has the highest incidence of SOC in Tildrakizumab(6/8), Guselkumab(5/20), Ustekinumab(50/107), Risankizumab(25/115). Conclusion: Our pharmacovigilance analysis showed that a high frequency was reported for AEs triggered by IL-23 inhibitors. IL-23 inhibitors had the potential to impair immune function resulting in a risk of infections or cancers. We need to pay special attention to Risankizumab because the drug has more AE occurrences than Ustekinumab despite Risankizumab has few reports than Ustekinumab and launched later than Ustekinumab.

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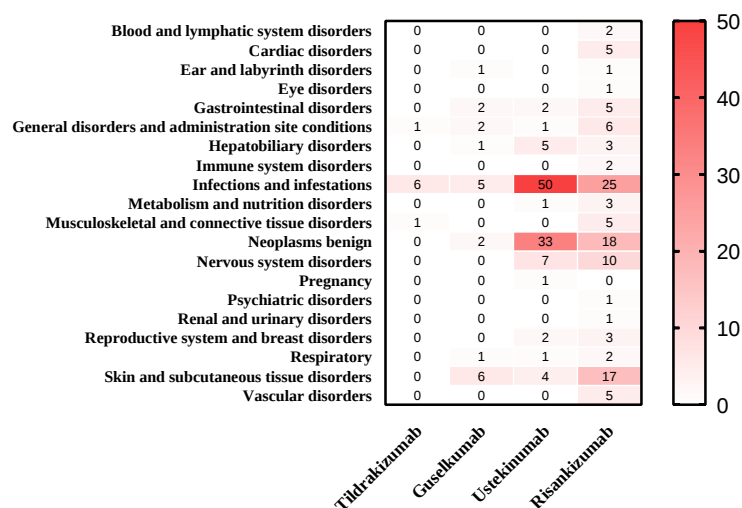


Figure 1 Heat map of adverse event signals of IL-23 inhibitors according to SOC

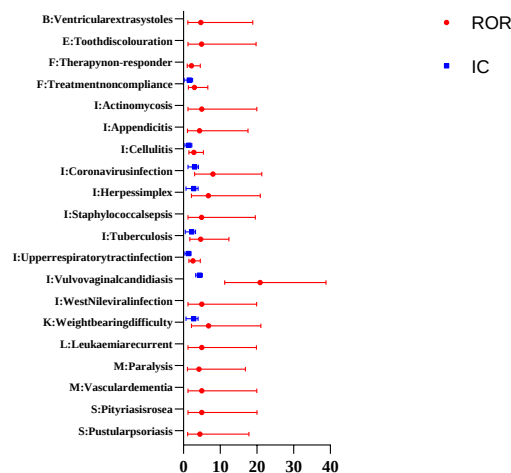


Figure 2 All signals of Tildrakizumab at the PT level

A-T before PT represents SOC Blood and lymphatic system disorders, Cardiac disorders, Ear and labyrinth disorders, Eye disorders, Gastrointestinal disorders, General disorders and administration site conditions, Hepatobiliary disorders, Immune system disorders, Infections and infestations, Metabolism and nutrition disorders, Musculoskeletal and connective tissue disorders, Neoplasms benign, malignant and unspecified (incl cysts and polyps), Nervous system disorders, Pregnancy, puerperium and perinatal conditions, Psychiatric disorders, Renal and urinary disorders, Reproductive system and breast disorders, Respiratory, thoracic and mediastinal disorders, Skin and subcutaneous tissue disorders, Vascular disorders respectively.

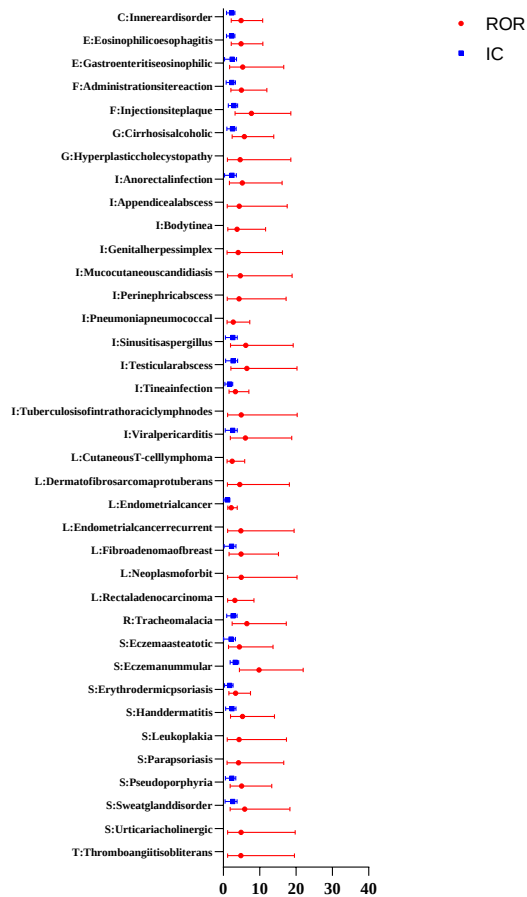


Figure 3 All signals of Guselkumab at the PT level

A-T before PT represents SOC Blood and lymphatic system disorders, Cardiac disorders, Ear and labyrinth disorders, Eye disorders, Gastrointestinal disorders, General disorders and administration site conditions, Hepatobiliary disorders, Immune system disorders, Infections and infestations, Metabolism and nutrition disorders, Musculoskeletal and connective tissue disorders, Neoplasms benign, malignant and unspecified (incl cysts and polyps), Nervous system disorders, Pregnancy, puerperium and perinatal conditions, Psychiatric disorders, Renal and urinary disorders, Reproductive system and breast disorders, Respiratory, thoracic and mediastinal disorders, Skin and subcutaneous tissue disorders, Vascular disorders respectively.

