SFDA SAFETY SIGNAL

"A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature"

28-03-2022

Saudi Food and Drug Authority (SFDA) – Safety Signal of Secukinumab and the Risk of Erectile Dysfunction (ED)

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Erectile Dysfunction** associated with the use of **Secukinumab**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Secukinumab is a recombinant, high-affinity, fully human immunoglobulin G1κ monoclonal antibody that selectively binds and neutralizes interleukin-17A [1]. Interleukin-17A is postulated to play a role in the pathogenesis of musculoskeletal autoimmune diseases. The drug is approved to treat Plaque psoriasis and shows efficacy in treatment of psoriatic arthritis and ankylosing spondylitis [1-2]. Erectile Dysfunction (ED) (a.k.a. Impotence) is the inability to get and keep an erection firm enough for sex [3]. ED may accompany chronic diseases such as hypertension, hyperlipidemia, diabetes mellitus, and depression [4]. The aim of this review is to evaluate the risk of ED associated with the use of Secukinumab and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at the National Pharmacovigilance Center (NPC) of Saudi Food and Drug Authority (SFDA) performed a comprehensive signal review using its national database as well as the World Health Organization (WHO) database (VigiBase), to retrieve related information for assessing the causality between Secukinumab and the risk of ED [5]. We used the WHO- Uppsala Monitoring Centre (UMC) criteria as standard for assessing the causality of the reported cases [6].

Results

Case Review: As of September, 2021, there were 37 global Individual case safety reports (ICSRs) for the combined drug/adverse drug reaction [5]. The reviewers selected cases with completeness score of 0.7 and above (n=9). Seven of the assessable ICSRs were supportive of association, with two being probable and five being possible. Positive dechallenge was reported in two cases [6].

Data Mining: Information component (IC), a tool developed by WHO-UMC to measure the reporting ratio, was used to estimate the disproportionality of the observed and expected reporting rates for drug/adverse drug reaction pairs. Positive IC reflects higher statistical association while negative values indicates less statistical association. The results of (IC= - 1.7) revealed a negative statistical association for the drug/ADR combination [5].

Literature: A 45-year-old male patient was started on Secukinumab 300 mg for active psoriasis relapsing on topical Calcipotriol/Betamethasone 50 mg/0.5 mg/g and Clobetasol propionate (0.05%). The treatment led to the complete resolution of the dermatologic condition. However, after 60 days of Secukinumab therapy, the patient experienced Erectile Dysfunction, but he ignored this persistent sign. Months after, he decided to seek urological consultation. Diagnosis of moderate Erectile Dysfunction has been confirmed in specialist clinic with no particular cause. The specialist decided to interrupt Secukinumab. Sixty days after the interruption, sexual dysfunction disappeared. Withholding Secukinumab for six months led to a reoccurrence of dermatologic manifestations of psoriasis, for which Secukinumab was prescribed again. After 60 days of Secukinumab administration, the patient reported Erectile Dysfunction for the second time and was switched to Ixekizumab [7].

Conclusion

The weighted cumulative evidence identified from the reported cases and literature are sufficient to support a causal association between Secukinumab and the risk of ED. Health regulators and health care professionals must be aware of this potential risk and it is advisable to monitor any signs or symptoms in treated patients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

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