

**08.10.2020 ANTI-TNF AJANLARI KAYNAKLI KAPOSİ SARKOMU RISKİ-ACİL GÜVENLİLİK
KISITLAMASI, ENG**

1 / 2

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency
of Turkey

**WITH DEADLINE
08.10.2020**

DOSSIER

The warning entitled “Tumor necrosis factor alpha inhibitors: adalimumab; certolizumab pegol; etanercept; golimumab; infliximab – Kaposi’s sarcoma”, published on August 3, 2020 on the official website of the European Medicines Agency and provided at the link in Annex 2 in relation with generation of a Kaposi’s Sarcoma risk by all medicines containing Anti-TNF agents including innovator medicines and biosimilars has been evaluated by our Agency. It is necessary to add the following statements presented in Annex 1 to the Summary of Product Characteristics (SPCs) and Package Leaflets (PLs) of the referred medicines which are registered in Turkey.

I hereby submit for your information and kindly request that the SPCs/PLs of all medicines containing Anti-TNF agents, including innovator medicines and their biosimilars, in which the referred changes are made are sent to the Pharmacological Evaluation Unit within 15 days as of the date of this announcement for review.

Assoc. Prof. Dr. Tolga TOLUNAY President of the Agency

Annex 1: Announcement to Association (1 page) Annex
2: https://www.ema.europa.eu/en/documents/prac-recommendation/new-product-information-wording-extracts-prac-recommendations-signals-adopted-6-9-july-2020-prac_en.pdf
Distribution: For the conduct of relevant action: Turkish Pharmaceutical Industry Association
Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers
Association of Turkey Association of Innovator Pharmaceutical Companies Health Products
Association No : 54398317-510.01.04-E.227734 Subject : Anti-TNF Agents / Kaposi’s Sarcoma /
Urgent Safety Restriction

2 | 2

[The following statements should be added to the summary of product characteristics and package leaflets of all medicines containing Anti-TNF agents (including innovator medicines and biosimilars). Relevant amendments should be made in case of any conflicting information with these statements.]

SUMMARY OF PRODUCT CHARACTERISTICS

4.8. Undesirable effects [The following statement should be added to the frequency “Unknown” under the title of “Benign, malignant and undefined neoplasms”.]
Kaposi’s Sarcoma

PACKAGE LEAFLET

[The following statement should be added to the frequency “Unknown” under the Heading of Relevant medicines “4. What are possible side effects?”]

- Kaposi’s Sarcoma is a rare cancer related to infection with Human Herpes Virus. Kaposi’s Sarcoma most commonly appears as purple lesions on the skin.