



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies, MOH
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Director General of Primary Health Care, MOH
Director General of Specialised Medical Care, MOH
Director General of Quality Assurance Centre, MOH
Director General of Disease Surveillance and Control, MOH
Director of Rational Drug Use
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 127 dated 01/07/2021
regarding **Atezolizumab (Tecentriq) and other immune-stimulatory anti-cancer drugs: risk of severe cutaneous adverse reactions (SCARs).**

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Section Head (Drug Information)



Circular No. 127 / 2021

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01 -07-2021

Atezolizumab (Tecentriq) and other immune-stimulatory anti-cancer drugs: risk of severe cutaneous adverse reactions (SCARs)

We would like to share an important drug safety information posted in the website of The Medicines and Healthcare products Regulatory Agency of the United Kingdom concerning the above mentioned drug. As per the report, cases of severe cutaneous adverse reactions, including Stevens-Johnsons syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in patients treated with immune-stimulatory anti-cancer drugs, including atezolizumab. MHRA advises patients to be vigilant for the signs of severe skin reactions and to seek urgent medical advice if they occur.

Advice for healthcare professionals:

- severe cutaneous adverse reactions (SCARs), including cases of Stevens-Johnsons syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in patients treated with immune-stimulatory anti-cancer drugs including atezolizumab
- advise patients of the need to seek urgent medical assistance if severe skin reactions occur
- monitor patients for signs and symptoms of severe skin reactions and exclude other causes
- if a SCAR is suspected, treatment should be withheld, and patients referred to a specialist for diagnosis and treatment
- if SJS or TEN is confirmed, or for any grade 4 (life-threatening) SCAR, permanently discontinue treatment with the immune-stimulatory drug
- caution is recommended when considering the use of immune-stimulatory drugs associated with SCARs in patients with previous history of life-threatening SCAR with other immune-stimulatory anti-cancer drugs

Advice for healthcare professionals to provide to patients:

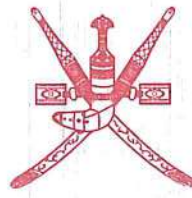
- contact doctor straight away in case of itching, skin blistering, peeling or sores, or ulcers in the mouth or in lining of nose, throat or genital area
- always read the leaflet that accompanies with medicines and talk to doctor, nurse, or pharmacist if concerned about any side effects

Review of atezolizumab and SCARs

Atezolizumab (Tecentriq) is an immune-stimulatory drug indicated for cancers including those of the bladder, lung, and liver.

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Severe cutaneous adverse reactions (SCARs) were previously known to be potentially associated with the use of atezolizumab. Based on evidence from a recent analysis, SCARs are now considered to be an identified risk for atezolizumab. The product information, including the Patient Information Leaflet, has been updated to include information about these reactions.

Although review of the cases worldwide found no reports of SCARs for patients on atezolizumab with a history of these reactions with another immune-stimulatory drug, healthcare professionals are advised to carefully consider the use of atezolizumab in patients who have had a severe or life-threatening SCAR following treatment with an immune-stimulatory anti-cancer drug.

Risk of SCARs with other immune-stimulatory drugs

Other products used for cancers in the same class as atezolizumab, including cemiplimab, ipilimumab, nivolumab, and pembrolizumab list SCARs (including SJS and TEN) as a possible side effects in the Summary of Product Characteristics (SmPC) with an associated warning and precautions. Avelumab and durvalumab are known to cause other immune-mediated skin adverse reactions. As for the other immune-stimulatory anti-cancer drugs, patients should be monitored for the signs and symptoms of serious skin reactions and treatment withheld or discontinued according to the severity of the event as described in the SmPC for each product.

Atezolizumab is registered in Oman.

Call to Report Suspected Adverse Drug Reactions

The healthcare professionals are encouraged to report any suspected adverse drug reactions to the Department of Pharmacovigilance & Drug Information in DGPA&DC.

Dr. Mohammed Hamdan Al Rubaie
Director General

