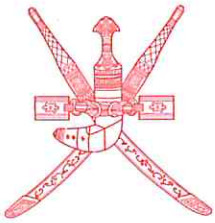
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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 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. 58 dated 25/03/2021 regarding EMA's report about COVID-19 Vaccine AstraZeneca.

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)

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 58 / 2021

11 -08-1442 H
25 -03-2021

COVID-19 Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets

We would like to share an important information published in the website of the European Medicines Agency (EMA) about COVID-19 vaccine AstraZeneca.

The EMA's safety committee, PRAC, concluded its preliminary review of a signal of blood clots in people vaccinated with COVID-19 Vaccine AstraZeneca at its extraordinary meeting of 18 March 2021. The Committee confirmed that:

- the benefits of the vaccine in combating the still widespread threat of COVID-19 (which itself results in clotting problems and may be fatal) continue to outweigh the risk of side effects;
- the vaccine is not associated with an increase in the overall risk of blood clots (thromboembolic events) in those who receive it;
- there is no evidence of a problem related to specific batches of the vaccine or to particular manufacturing sites;
- however, the vaccine may be associated with very rare cases of blood clots associated with thrombocytopenia, i.e. low levels of blood platelets (elements in the blood that help it to clot) with or without bleeding, including rare cases of clots in the vessels draining blood from the brain (CVST).

According to the report, these are rare cases – around 20 million people in the UK and EEA had received the vaccine as of March 16 and EMA had reviewed only 7 cases of blood clots in multiple blood vessels (disseminated intravascular coagulation, DIC) and 18 cases of CVST. A causal link with the vaccine is not proven, but is possible and deserves further analysis.

The Committee was of the opinion that the vaccine's proven efficacy in preventing hospitalization and death from COVID-19 outweighs the extremely small likelihood of developing DIC or CVST. However, in the light of its findings, patients should be aware of the remote possibility of such syndromes, and if symptoms suggestive of clotting problems occur patients should seek immediate medical attention and inform healthcare professionals of their recent vaccination. Steps are already being taken to update the product information for the vaccine to include more information on these risks.

The PRAC will undertake additional review of these risks, including looking at the risks with other types of COVID-19 vaccines (although no signal has been identified from monitoring so far). Close safety monitoring of reports of blood clotting disorders will continue, and further studies are being instituted to provide more laboratory data as well as real-world evidence. EMA will communicate further as appropriate.

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Information for healthcare professionals

- Cases of thrombosis and thrombocytopenia, some presenting as mesenteric vein or cerebral vein/cerebral venous sinus thrombosis, have been reported in persons who had recently received COVID-19 Vaccine AstraZeneca, mostly occurring within 14 days after vaccination. The majority of reports involved women under 55, although some of this may reflect greater exposure of such individuals due to targeting of particular populations for vaccine campaigns in different Member States.
- The number of reported events exceeds those expected, and causality although not confirmed, cannot therefore be excluded. However, given the rarity of the events, and the difficulty of establishing baseline incidence since COVID-19 itself is resulting in hospitalisations with thromboembolic complications, the strength of any association is uncertain.
- EMA considers that the benefit-risk balance of the medicine remains positive, and there is no association with thromboembolic disorders overall. However, steps will be taken to update the SmPC and package leaflet with information on cases of DIC and CVST that have occurred.
- Healthcare professionals are urged to be alert for possible cases of thromboembolism, DIC or CVST occurring in vaccinated individuals.
- Recipients should be warned to seek immediate medical attention for symptoms of thromboembolism, and especially signs of thrombocytopenia and cerebral blood clots such as easy bruising or bleeding, and persistent or severe headache, particularly beyond 3 days after vaccination.

Information for patients

- COVID-19 Vaccine AstraZeneca is not associated with an increased overall risk of blood clotting disorders.
- There have been very rare cases of unusual blood clots accompanied by low levels of blood platelets (components that help blood to clot) after vaccination. The reported cases were almost all in women under 55.
- Because COVID-19 can be so serious and is so widespread, the benefits of the vaccine in preventing it outweigh the risks of side effects.
- However, in case any of the following symptoms after receiving the COVID-19 Vaccine AstraZeneca, seek prompt medical assistance and mention about the recent vaccination:
    - breathlessness,
    - pain in the chest or stomach,
    - swelling or coldness in an arm or leg,
    - severe or worsening headache or blurred vision after vaccination,
    - persistent bleeding,
    - multiple small bruises, reddish or purplish spots, or blood blisters under the skin

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More about the medicine
COVID-19 Vaccine AstraZeneca is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older. COVID-19 is caused by SARS-CoV-2 virus. COVID-19 Vaccine AstraZeneca is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2. COVID-19 Vaccine AstraZeneca does not contain the virus itself and cannot cause COVID-19.

The most common side effects with COVID-19 Vaccine AstraZeneca are usually mild or moderate and improve within a few days after vaccination.

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

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DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL