ACE inhibitors and ARB medicines:
Continued use during COVID-19 pandemic

18.06.2020 | Circular Number P19.2020

Information on Angiotensin Converting Enzyme inhibitors and Angiotensin Receptor Blockers

- Angiotensin Converting Enzyme inhibitors (ACEi) and Angiotensin receptor blockers (ARBs) are used for treating patients with high blood pressure, heart problems or kidney disease.

These products are authorised in Malta through different procedures.

Information from the EMA

In April 2020, media outlets and publications raised concerns about the effects of these medicines in patients with COVID-19. As part of the ongoing monitoring of the safety of medicines, 16 recently published studies on the use of ACE inhibitors and ARBs during the COVID-19 pandemic were reviewed and showed that these concerns are not supported by the latest clinical evidence.

Recent observational studies of ACEi and ARBs (also called sartans) have not shown an effect of these medicines on the risk of becoming infected with severe acute respiratory syndrome coronavirus 2 (the virus causing COVID-19) and do not indicate a negative impact on the outcome for patients with COVID-19 disease.

EMA reiterates its previous advice that patients should continue to use ACE inhibitors or ARBs as advised by their doctors. Patients with questions or concerns about their treatment should consult a healthcare professional.

EMA and the EU regulatory network will continue monitoring available and emerging data on the use of medicines during the ongoing COVID-19 pandemic and is working with other regulators and relevant European and international organisations to provide reliable advice on the safe use of medicines.

Further information on recommendations about COVID-19 is available on European Medicines Agency's website and the Medicines Authority website.

This public health statement has been issued by the COVID-19 EMA pandemic Task Force (COVID-ETF).

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on ACEi and ARB containing medicinal products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

Postage will be paid
by the Licensee

No postage stamp
necessary if posted
in Malta and Gozo

BUSINESS REPLY SERVICE
Licence no. 656

Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

Malta Life Sciences Park

San Ġwann SĠN 3000