

EMA advices on use of medicines for hypertension, heart or kidney diseases during COVID-19 pandemic

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Information on non-steroidal anti-inflammatory medicines, angiotensin converting enzyme inhibitors and angiotensin receptor blockers

- Non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen and ketoprofen, are authorised as painkillers and, in some countries as antipyretic (fever medicines). These medicines are available over the counter and on prescription
- Angiotensin converting enzyme inhibitors (ACEi) are medicines used to treat patients with high blood pressure, heart problems and other conditions. ACEi act by preventing the production of angiotensin II, a hormone that narrows blood vessels leading to increase in blood pressure and causing the heart to work harder. Angiotensin II also releases other hormones that increase blood pressure
- Angiotensin receptor blockers (ARBs or sartans) are medicines used to treat patients with high blood pressure, certain heart and kidney diseases and complications such as diabetic nephropathy. ARBs act by blocking the action of angiotensin II, therefore preventing the narrowing of blood vessels

Information from the EMA about continuing the use medicines for hypertension, heart or kidney disease during COVID-19 pandemic

EMA is aware of recent media reports and publications¹ which questions if medicines, in particular ACEi, ARBs and NSAIDs, could worsen coronavirus disease (COVID-19). EMA's recommendations on the matter are as follows:

- Patients and healthcare professionals can continue using NSAIDs (like ibuprofen) as per approved product information. Current advice includes that these medicines are used at the lowest possible dose, for the shortest possible period
- NSAIDs can be considered as an option to start treatment for fever and pain in COVID-19. Each medicine has its own risk and benefits which are reflected in the product information and that should be considered along with EU national treatment guidelines, most of which recommend paracetamol as first line treatment for fever and pain
- Patients should continue treatment with ACEi and ARBs. Currently, there is no evidence from clinical and epidemiological studied that establishes a link between ACEi or ARBs and worsening of COVID-19. Experts in the treatment of heart and blood

¹ https://www.thelancet.com/pdfs/journals/lanres/PIIS2213-2600(20)30116-8.pdf



pressure disorders, including the European Society of Cardiology, have already issued their statements along this line ^{2, 3}

- ACEi and ARBs act by affecting the renin-angiotensin-aldosterone system (RAAS). The angiotensin converting enzyme 2 (ACE2), which is targeted by SARS-COV-2 to enter human cells, is part of RAAS and can be increase by ACEi and ARBs. However, the interactions of the virus with the RAAS are complex and not completely understood
- NSAIDs, ACEi and ARBs should not be stopped by patients. Patients who have any questions or are uncertain about their medicines should speak with their doctor or pharmacist

For more information, visit the European Medicines Agency's <u>NSAIDs press release</u> and <u>ACEi</u> and <u>ARBs press release</u>.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on NSAIDs medicinal products and ACEi and ARBs 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 <u>http://www.medicinesauthority.gov.mt/adrportal</u> 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.

² <u>https://www.escardio.org/Councils/Council-on-Hypertension-(CHT)/News/position-statement-of-the-esc-council-on-hypertension-on-ace-inhibitors-and-ang</u>

³ https://www.acc.org/latest-in-cardiology/articles/2020/03/17/08/59/hfsa-acc-aha-statement-addresses-concerns-re-using-raas-antagonists-in-covid-19

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.

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