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EMA advises continued use of medicines for hypertension, heart or kidney disease during COVID-19 pandemic

EMA is aware of recent media reports and publications¹ which question whether some medicines, for instance angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs, or sartan medicines), could worsen coronavirus disease (COVID-19). ACE inhibitors and ARBs are most commonly used for treating patients with high blood pressure, heart failure or kidney disease.

It is important that patients do not interrupt their treatment with ACE inhibitors or ARBs and there is no need to switch to other medicines. There is currently no evidence from clinical or epidemiological studies that establishes a link between ACE inhibitors or ARBs and the worsening of COVID-19. Experts in the treatment of heart and blood pressure disorders, including the European Society of Cardiology, have already issued statements along those lines.^{2,3} To gather more evidence, EMA is proactively reaching out to researchers working to generate further evidence in epidemiological studies.

As the public health crisis rapidly extends across the globe, scientific research is ongoing to understand how the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reproduces in the body, interacts with the immune system and causes disease, and whether ongoing treatment with medicines such as ACE-inhibitors and ARBs could impact the prognosis of COVID-19.

The speculation that ACE-inhibitors or ARBs treatment can make infections worse in the context of COVID-19 is not supported by clinical evidence. These medicines work by affecting the reninangiotensin-aldosterone system (RAAS). Because the virus uses a target called angiotensin converting enzyme 2 (ACE2), which is part of this system, to enter human cells, and the medicines can increase ACE2, one of the suggestions among others is that they could also increase virus activity. However, the interactions of the virus with the RAAS in the body are complex and not completely understood.

EMA is monitoring the situation closely and is collaborating with stakeholders to coordinate epidemiological studies on the effects of ACE inhibitors and ARBs in people with COVID-19.

EMA is helping to coordinate urgent ongoing research and is fully committed to keep the public up to date with any development in this field. EMA is also aware of reports questioning whether other

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>

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

³ <u>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</u>

medicines such as corticosteroids and non-steroidal anti-inflammatories (NSAIDs) could worsen COVID-19, and has recently issued a communication on <u>NSAIDs</u> medicines. It is important that patients who have any questions or are uncertain about their medicines speak to their doctor or pharmacist and do not stop their regular treatment without speaking to their healthcare professional first.

Medicines should be prescribed and used in line with clinical judgement, taking due note of any warnings and other information provided in the summary of product characteristics (SmPC) and the package leaflet, as well as guidance issued by the WHO and relevant national and international bodies.

Within the EU medicines regulatory network, evidence on the safe use of medicines is reviewed as it emerges. Any new advice that arises is disseminated appropriately through <u>EMA</u> and <u>national</u> <u>competent authorities</u>.

EMA will provide further information as appropriate.

More about the medicines

Angiotensin converting enzyme (ACE) inhibitors are medicines used to treat patients with high blood pressure, heart problems and other conditions. They have active ingredients whose names generally end in "pril". ACE inhibitors prevent an enzyme in the body from producing angiotensin II, a hormone that narrows blood vessels. This narrowing can cause high blood pressure and force the heart to work harder. Angiotensin II also releases other hormones that raise blood pressure.

Angiotensin receptor blockers (ARBs, also known as angiotensin-II-receptor antagonists or sartans) are used to treat patients with high blood pressure and those with certain heart or kidney diseases and complications such as diabetic nephropathy. They also work by blocking the action of angiotensin II, preventing blood vessels from constricting so that blood pressure does not rise.

Corticosteroids, often known as steroids, are anti-inflammatory medicines prescribed for a wide range of conditions such as asthma, allergic rhinitis, chronic obstructive pulmonary disease (COPD), Crohn's disease, ulcerative colitis and many more. Corticosteroids work in the same way as hormones normally produced by the adrenal glands (two small glands that sit on top of the kidneys). They are mainly used to reduce inflammation and suppress the immune system.

Ibuprofen, a non-steroidal anti-inflammatory medicine, is a painkiller and an antipyretic (fever medicine). Oral ibuprofen is used, depending on the presentation, in adults, children and infants from the age of three months for the short-term treatment of fever and/or pain such as headaches, flu aches, dental pain and dysmenorrhoea (period pain). Ibuprofen is also prescribed for the treatment of arthritis and rheumatic conditions.