

18 March 2020 EMA/136850/2020

EMA gives advice on the use of non-steroidal antiinflammatories for COVID-19

EMA is aware of reports, especially on social media, which raise questions about whether non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen could worsen coronavirus disease (COVID-19).

There is currently no scientific evidence establishing a link between ibuprofen and worsening of COVID-19. EMA is monitoring the situation closely and will review any new information that becomes available on this issue in the context of the pandemic.

In May 2019, EMA's safety committee (PRAC) started a review of the non-steroidal anti-inflammatory medicines ibuprofen and ketoprofen following a <u>survey</u> by the French National Agency for Medicines and Health Products Safety (ANSM) which suggested that infection due to chickenpox (varicella) and some bacterial infections could be made worse by these medicines. The product information of many NSAIDs already contains warnings that their anti-inflammatory effects may hide the symptoms of a worsening infection. The PRAC is reviewing all available data to see if any additional measure is required.

When starting treatment for fever or pain in COVID-19, patients and healthcare professionals should consider all available treatment options including paracetamol and NSAIDs. Each medicine has its own benefits and risks which are reflected in its product information and which should be considered along with EU national treatment guidelines, most of which recommend paracetamol as a first treatment option for fever or pain.

In line with EU national treatment guidelines, patients and healthcare professionals can continue using NSAIDs (like ibuprofen) as per the approved product information. Current advice includes that these medicines are used at the lowest effective dose for the shortest possible period.

Patients who have any questions should speak to their doctor or pharmacist. There is currently no reason for patients taking ibuprofen to interrupt their treatment, based on the above. This is particularly important for patients taking ibuprofen or other NSAID medicines for chronic diseases.

Further to the ongoing PRAC safety review on ibuprofen and ketoprofen, EMA highlights the need for epidemiological studies to be conducted in a timely manner to provide adequate evidence on any effect of NSAIDs on disease prognosis for COVID-19. The Agency is reaching out to its stakeholders and is ready to actively support such studies, which could be useful in guiding any future treatment recommendations.



EMA will provide further information as necessary and once the PRAC review is concluded.

More about the medicines

Most ibuprofen-containing medicines in the EU are authorised at national level, as a painkiller and in some countries also as an antipyretic (fever medicine). They are widely available over the counter and on prescription. Oral ibuprofen (over the counter or with a prescription) 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, dental pain and dysmenorrhoea (period pain). Ibuprofen is also prescribed for the treatment of arthritis and rheumatic conditions. Ketoprofen is a similar medicine, mostly prescribed for use in various painful and inflammatory conditions although in some Member States it is available over the counter.

Ibuprofen has also been authorised centrally as Pedea to treat 'patent ductus arteriosus' in newborn premature babies.

More about the procedure

The review of ibuprofen and ketoprofen is carried out in the context of a safety signal procedure. A safety signal is new information on the safety of a medicine that requires further investigation and is not itself evidence of a causal relationship between a medicine and the side effect concerned.