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EMA starts evaluating use of Olumiant in hospitalised COVID-19 patients requiring supplemental oxygen

EMA has started evaluating an application to extend the use of Olumiant (baricitinib) to include treatment of COVID-19 in hospitalised patients from 10 years of age who require supplemental oxygen.

Olumiant is an immunosuppressant (a medicine that reduces the activity of the immune system). It is currently authorised for use in adults with moderate to severe rheumatoid arthritis or atopic dermatitis (eczema). Its active substance, baricitinib, blocks the action of enzymes called Janus kinases that play an important role in immune processes that lead to inflammation. It is thought that this could also help reduce the inflammation and tissue damage associated with severe COVID-19 infection.

EMA's human medicines committee (CHMP) will carry out an accelerated assessment of data submitted by the company that markets Olumiant, including results from 2 large randomised studies in patients hospitalised with COVID-19, in order to recommend as soon as possible whether or not the extension of indication should be authorised. The CHMP's opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

EMA will communicate on the outcome of its evaluation, which is expected to reach an opinion by July unless supplementary information is needed.

Olumiant was first authorised in the EU in February 2017. More information about the medicine is available on EMA's website.

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