14 September 2023
EMA/533949/2023
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): (1r,2s,5s)-n-{(1s)-1-cyano-2-[(3s)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3- [3-methyl-n-(trifluoroacetyl)-l-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide / ritonavir (Paxlovid)

Procedure No. EMEA/H/C/PSUSA/00010984/202212

Period covered by the PSUR:
01 July 2022 To: 31 December 2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for (1r,2s,5s)-n-{(1s)-1-cyano-2-[(3s)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3- [3-methyl-n-(trifluoroacetyl)-l-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide / ritonavir (Paxlovid), the scientific conclusions of PRAC are as follows:

In view of available data on dysgeusia from the literature and spontaneous reports, including a high number of patients specifying the altered taste as metallic, bitter taste, the PRAC considers that a more precise description of dysgeusia in section 4 of the PL may be useful for patients. The PRAC concluded that the product information of products containing nirmatrelvir/ritonavir should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for (1r,2s,5s)-n-{(1s)-1-cyano-2-[(3s)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3- [3-methyl-n-(trifluoroacetyl)-l-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide / ritonavir (Paxlovid) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing (1r,2s,5s)-n-{(1s)-1-cyano-2-[(3s)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3- [3-methyl-n-(trifluoroacetyl)-l-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide / ritonavir (Paxlovid) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.