Paxlovid®

(nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets)

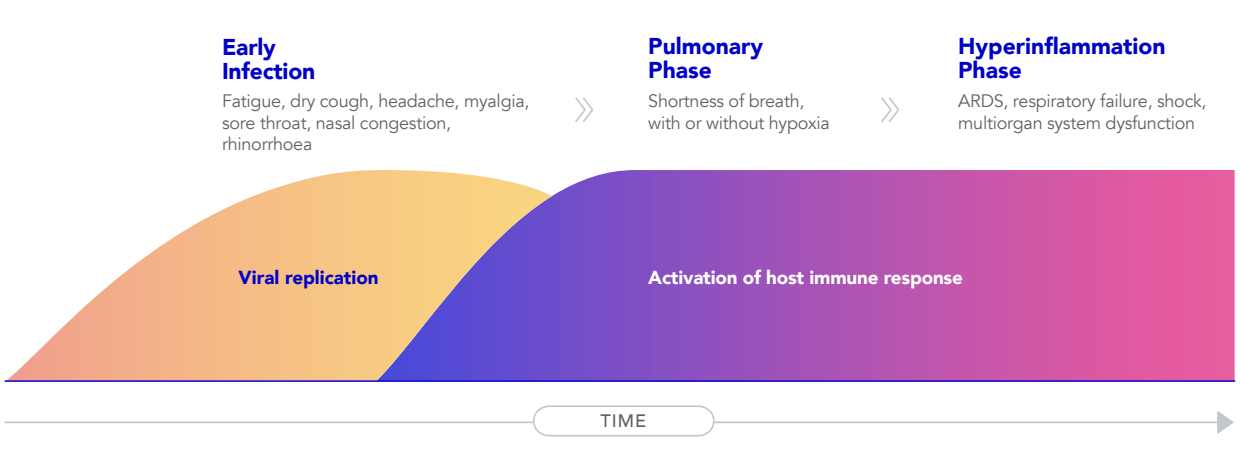
PAXLOVID® is indicated for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19.[1,2]

The importance of identifying patients who are at the highest risk for progression to severe COVID-19

Paxlovid (nirmatrelvir/ritonavir) has a Conditional Marketing Authorisation (CMA) in Great Britain.[1]

A CMA means that further evidence on this medicinal product is awaited. New information on this medicinal product will be reviewed when any relevant information of significance becomes available and at least every year, and the product information will be updated as necessary.[1]

SARS-CoV-2 replicates quickly, and COVID-19 can become severe for those with high risk factors[3–5]



Median time to severe COVID-19

8 days from symptom onset[5]

Treat eligible high-risk patients before their mild-moderate COVID-19 progresses, which could lead to hospitalisation and potentially death[5]

High-risk patients can quickly progress to severe disease, underscoring the need for rapid therapeutic intervention[4,5]

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The following groups should be considered at the highest risk of severe COVID-19, according to the independent Advisory Group report commissioned by the Department of Health and Social Care:[6]

Down's syndrome and other chromosomal disorders known to affect immune competence

Solid cancers

Haematological diseases or HSCT recipients, including sickle cell disease

Renal disease: chronic kidney disease (CKD) stage 4 or 5

Paxlovid is contraindicated in patients with severe renal impairment (GB)[1]
Paxlovid should not be used in patients with severe renal impairment [eGFR <30 mL/min, including patients with End Stage Renal Disease (ESRD) under haemodialysis] (NI)[2]

Liver diseases

Paxlovid is contraindicated in patients with severe hepatic impairment (GB)[1]
Paxlovid should not be used in patients with severe (Child-Pugh Class C) hepatic impairment (NI)[2]

Solid organ transplant recipients

Immune-mediated inflammatory disorders

Respiratory conditions

Immune deficiencies

HIV/AIDS who have a weakened immune system

Neurological disorders

The decision to treat and choice of treatment is down to the individual prescriber's discretion.

Adapted from Defining the highest-risk clinical subgroups upon community infection with SARS-CoV-2 when considering the use of neutralising monoclonal antibodies (nMABs) and antiviral drugs (updated March 2023): independent advisory group report.[6]

Refer to the Paxlovid GB or NI SmPCs for further information including contraindications, special warnings and precautions for use, information on interactions, adverse events and prescribing in special populations.

Additional information on the highest risk patients at risk of progression to severe COVID-19

Adverse Events

Adverse Events should be reported. Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse Events should also be reported to Pfizer Medical Information on 01304 616161.

Paxlovid (nirmatrelvir/ritonavir) Prescribing Information:

Great Britain
Paxlovid (nirmatrelvir/ritonavir)

Paxlovid (nirmatrelvir/ritonavir) Prescribing Information:

Northern Ireland
Paxlovid (nirmatrelvir/ritonavir)

Abbreviations:
AIDS, acquired immune deficiency syndrome; **ARDS,** acute respiratory distress syndrome; **COVID-19,** coronavirus disease 2019; **eGFR,** estimated glomerular filtration rate; **HIV,** human immunodeficiency virus; **HSCT,** haematopoietic stem cell transplantation; **SARS-CoV-2,** severe acute respiratory syndrome coronavirus 2.

References:
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1. PAXLOVID® Summary of Product Characteristics. Great Britain. Available at: https://www.medicines.org.uk/emc/product/13145.
2. PAXLOVID® Summary of Product Characteristics. Northern Ireland. Available at: https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf.
3. Siddiqi H, Mehra M. *J Heart Lung Transplant*. 2020; 39(5): 405–407.
4. NHS UK. COVID-19 symptoms and what to do. Available at: https://www.nhs.uk/conditions/coronavirus-covid-19/symptoms/main-symptoms/ (Accessed: May 2023).
5. Bestetti R, Furlan-Daniel R, Silva V. *Int J Environ Res Public Health*. 2021; 18(13): 7212.
6. GOV.UK. Defining the highest-risk clinical subgroups upon community infection with SARS-CoV-2 when considering the use of neutralising monoclonal antibodies (nMABs) and antiviral drugs: independent advisory group report. Available at: https://www.gov.uk/government/publications/higher-risk-patients-eligible-for-covid-19-treatments-independent-advisory-group-report-march-2023/defining-the-highest-risk-clinical-subgroups-upon-community-infection-with-sars-cov-2-when-considering-the-use-of-neutralising-monoclonal-antibodies (Accessed: May 2023).

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Northern Ireland: Marketing Authorisation Number: EU/1/22/1625/001. Marketing Authorisation Holder: Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Brussels, Belgium.

Further Information is available on request from: Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Tel +44 (0)1304 616161.

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