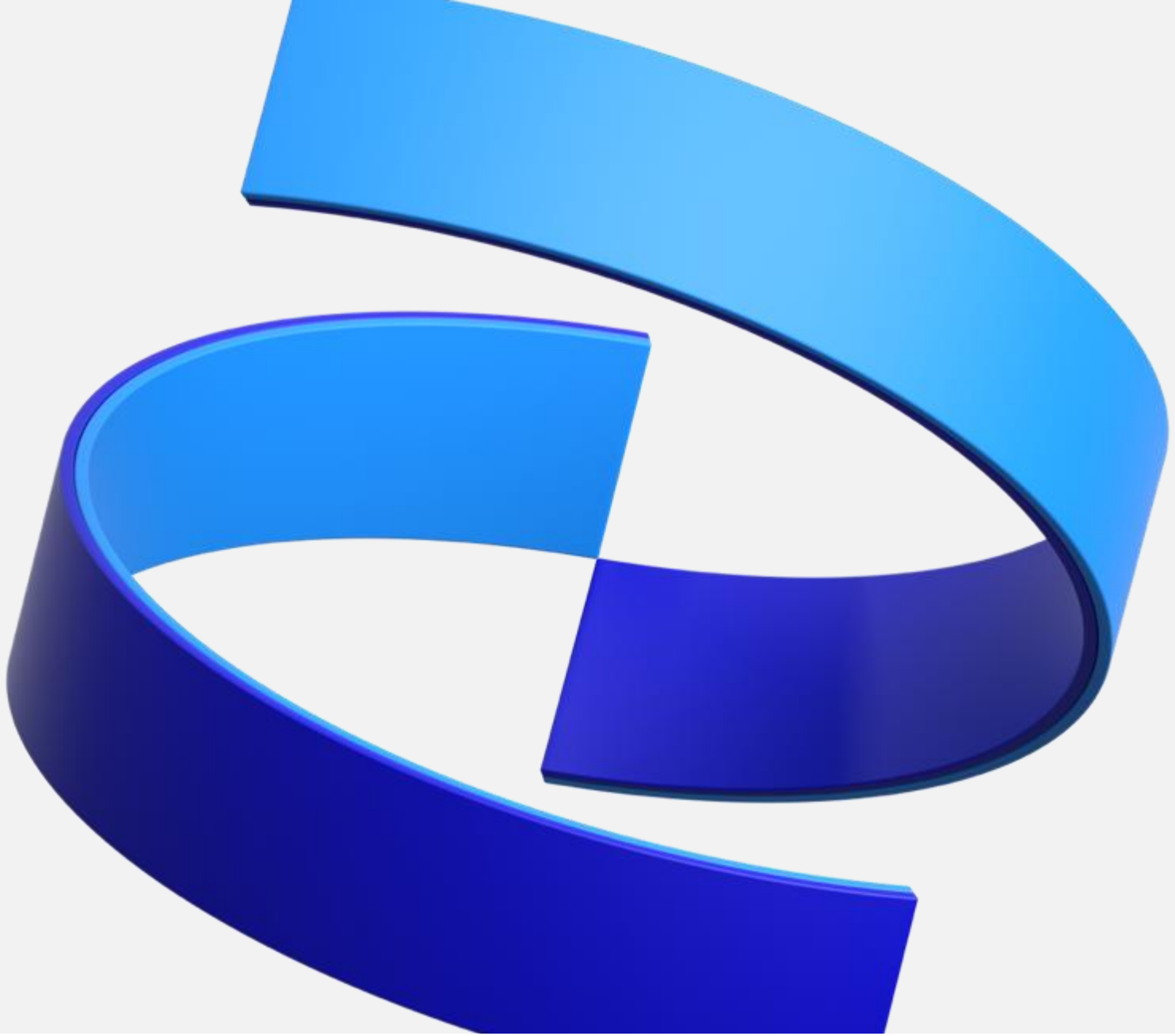
WONCA
27th European Congress

Pfizer promotional symposium

June 29th 2022; 12:30–13:30

PAXLOVID®▼(nirmatrelvir 150mg/ritonavir 100mg) (known in Northern Ireland as PAXLOVID®▼ (PF-07321332 150mg/ritonavir 100mg)) has received Conditional Marketing Authorisation (CMA) 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.

A Conditional Marketing Authorisation (CMA) means that further evidence on this medicinal product is awaited. New information on this medicinal product will be reviewed at least every year and the product information will be updated as necessary.
This promotional meeting is organised & funded by Pfizer Ltd. Please note that, under the law and the ABPI Code of Practice, Pfizer may only promote its medicines and provide hospitality to members of the healthcare professions and other relevant decision makers. Therefore, no unqualified person (e.g. students, non-medical spouses/partners/family members) may be invited to or attend Pfizer promotional meetings.



PP-PAX-GBR-0103
Date of preparation: June 2022

Symposium title:

Innovating COVID-19 Approaches for a Sustainable Future

Objectives:

- **To emphasise the beneficial impact on COVID-19 patient outcomes through early detection and intervention**
- **To highlight the current understanding of the ‘high-risk’ patient, including important comorbidities and medical factors**
- **Increase awareness of the current COVID-19 interventions targeting the SARS-CoV-2 viral lifecycle at its various stages**
- **Hold an expert-led discussion regarding the critical importance of early diagnosis, referral and access to treatments for COVID-19**

Time	Session	Speaker
12:45–12:50	**Welcome and introduction**	Brian O’Doherty, Ireland
12:50–13:10	**Improving COVID-19 outcomes through early detection and intervention**	Luis Buzón-Martín, Spain Luke Moore, UK
13:10–13:25	**Identification of COVID-19 ‘high-risk’ patients**	Luke Moore, UK
13:25–13:30	**Q&A and close**	Brian O’Doherty, Ireland

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Adverse events should be reported. Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/ or search MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Pfizer Medical Information on 01304 616161 or via www.pfizersafetyreporting.com.

GREAT BRITAIN PRESCRIBING INFORMATION

GB prescribing information may differ from local prescribing information and local prescribing information should be consulted

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

Paxlovid™▼(nirmatrelvir/ritonavir) 150 mg/100 mg film-coated tablets
Please refer to the Summary of Product Characteristics (SmPC) before prescribing Paxlovid.

Indications: Treatment of COVID 19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID 19 (see section 5.1 of the SmPC). **Presentation:** Each pink nirmatrelvir film-coated tablet contains 150 mg of nirmatrelvir. Each white ritonavir film-coated tablet contains 100 mg of ritonavir. **Dosage:** The recommended dosage is 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) all taken together orally twice daily for 5 days. Paxlovid should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 5 days of onset of symptoms. In patients with moderate renal impairment, the dose of Paxlovid should be reduced to nirmatrelvir/ritonavir 150 mg/100 mg (1 tablet of each) twice daily for 5 days. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. Severe hepatic or severe renal impairment. Medicinal products that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening reactions, as well as medicinal product that are potent CYP3A inducers where significantly reduced plasma nirmatrelvir/ritonavir concentrations may be associated with the potential for loss of virologic response and possible resistance: *Alpha 1 adrenoreceptor antagonist:* alfuzosin; *Analgesics:* pethidine, piroxicam, propoxyphene; *Antianginal:* ranolazine; *Anticancer:* neratinib, venetoclax (in some circumstances); *Antiarrhythmics:* amiodarone, bepridil, dronedarone, encainide, flecainide, propafenone, quinidine; *Antibiotic:* fusidic acid; *Anti-gout:* colchicine; *Antihistamines:* astemizole, terfenadine; *Antipsychotics/Neuroleptics:* lurasidone, pimozide, clozapine, quetiapine; *Ergot derivatives:* dihydroergotamine, ergonovine, ergotamine, methylergonovine; *GI motility agent:* cisapride; Lipid-modifying agents: lovastatin, simvastatin, lomitapide; *PDE5 inhibitors:* avanafil, vardenafil, sildenafil when used for pulmonary arterial hypertension (PAH); *Sedative/Hypnotics:* clonazepam, diazepam, estazolam, flurazepam, triazolam, oral midazolam; *Anticonvulsants:* carbamazepine, phenobarbital, phenytoin; *Antimycobacterials:* rifampin; *Herbal products:* St. John's Wort (*Hypericum perforatum*). Please refer to Table 1 in SmPC section 4.3 for additional information. **Warnings and Precautions:** Risk of serious adverse reactions due to interactions with other medicinal products: Due to effects on CYP3A metabolic pathways, potential for interactions should be considered with other medicinal products prior to and during Paxlovid therapy; concomitant medicinal products should be reviewed during Paxlovid therapy and the patient should be monitored for the adverse reactions associated with the concomitant medicinal products. The risk of interactions with concomitant medications during the 5-day treatment period for Paxlovid should be weighed against the risk of not receiving Paxlovid; please refer to Table 2 in SmPC section 4.5. *Hepatotoxicity:* Caution should be exercised when administering Paxlovid to patients with pre-existing liver diseases, liver enzyme abnormalities or hepatitis. *HIV resistance:* As nirmatrelvir is coadministered with ritonavir, there may be a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection. *Excipients:* Nirmatrelvir tablets contain lactose, patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine. Contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. **Drug Interactions:** Nirmatrelvir and ritonavir are CYP3A substrates; therefore, medicinal products that induce CYP3A may decrease plasma concentrations of nirmatrelvir and ritonavir and reduce therapeutic effect. Paxlovid is an inhibitor of CYP3A and may increase plasma concentrations of medicinal products that are primarily metabolised by CYP3A. Ritonavir has a high affinity for several cytochrome P450 (CYP) isoforms and may inhibit oxidation with the following ranked order: CYP3A4 > CYP2D6. Ritonavir also has a high affinity for P glycoprotein (P-gp) and may inhibit this transporter. Ritonavir may induce glucuronidation and oxidation by CYP1A2, CYP2C8, CYP2C9 and CYP2C19 thereby increasing the biotransformation of some medicinal products metabolised by these pathways. Medicinal products listed here are a guide and not considered a comprehensive list of all possible medicinal products that may interact with nirmatrelvir/ritonavir: *Amphetamine derivatives:* methylphenidate, dexamfetamine; *Analgesics:* buprenorphine, norbuprenorphine, fentanyl, methadone, morphine; *Antiarrhythmics:* digoxin; Antiasthmatic: theophylline; *Anticancer:* afatinib, abemaciclib, apalutamide, ceritinib, dasatinib, nilotinib, vincristine, vinblastine, encorafenib, fostamatinib, ibrutinib, venetoclax (contraindicated in some circumstances*); Anticoagulants:* apixaban, dabigatran, rivaroxaban, vorapaxar, warfarin; *Anticonvulsants:* divalproex, lamotrigine, phenytoin; *Antidepressants:* amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline, desipramine; *Antihistamines:* fexofenadine, loratadine; *Anti-infectives:* rifabutin, voriconazole, ketoconazole, itraconazole, erythromycin, atovaquone, bedaquiline, delamanid, clarithromycin, sulfamethoxazole/trimethoprim*; Anti-HIV:* amprenavir, atazanavir, darunavir, fosamprenavir, efavirenz, maraviroc, raltegravir, zidovudine; *Antipsychotics:* haloperidol, risperidone, thioridazine; *β2-agonist (long acting):* salmeterol; *Calcium channel antagonist:* amlodipine, diltiazem, nifedipine; Endothelin antagonists: bosentan, riociguat; *HCV direct acting antiviral:* glecaprevir/pibrentasvir; *HMG Co-A reductase:* atorvastatin, fluvastatin, pravastatin, rosuvastatin; *Hormonal contraceptive:* ethinylestradiol; *Immunosuppressants:* cyclosporine, tacrolimus, everolimus; *PDE5 inhibitors:* sildenafil (contraindicated when used for PAH), tadalafil; *Sedatives/Hypnotics:* parenteral midazolam, alprazolam, buspirone; *Sleeping agent:* zolpidem; *Smoke cessation:* buproprion; *Steroids:* inhaled, injectable or intranasal fluticasone propionate, budesonide, triamcinolone, dexamethasone, prednisolone*; Thyroid hormone replacement therapy:* levothyroxine. Please refer to Table 2 in SmPC section 4.5 for additional information on interaction with medicinal products and other forms of interaction. **Fertility, pregnancy and lactation:** Paxlovid is not recommended during pregnancy and in women of childbearing potential not using effective contraception. Patients using combined hormonal contraceptives should be advised to use an effective alternative contraceptive method or an additional barrier method of contraception during treatment and until after one complete menstrual cycle after stopping Paxlovid. Breast feeding should be discontinued during treatment with Paxlovid and for 7 days after the last dose. **Driving and operating machinery:** There are no clinical studies that evaluated the effects of Paxlovid on ability to drive and use machines. **Undesirable effects:** Common (≥ 1/100 to < 1/10) adverse events reported were dysgeusia, diarrhoea and vomiting. See SmPC section 4.8 for full details.

Legal Category: POM. **Package Quantities:** 150 mg + 100 mg, 20 + 10 film coated tablets. **Marketing Authorisation Number:** PLGB 00057/1710. **NHS price:** Not applicable. **Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, UK. 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

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard 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

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Ref: PX 1_0

NORTHERN IRELAND PRESCRIBING INFORMATION

NI prescribing information may differ from local prescribing information and local prescribing information should be consulted

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

Paxlovid™▼(PF-07321332/ritonavir) 150 mg + 100 mg film-coated tablets
Please refer to the Summary of Product Characteristics (SmPC) before prescribing Paxlovid.

Indications: Treatment of coronavirus disease 2019 (COVID-19) in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID 19 (see section 5.1 of the SmPC). **Presentation:** Each pink film-coated tablet contains 150 mg of PF 07321332. Each white film-coated tablet contains 100 mg of ritonavir. **Dosage:** The recommended dosage is 300 mg PF 07321332 (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) all taken together orally every 12 hours for 5 days. Paxlovid should be administered as soon as possible after a diagnosis of COVID-19 and within 5 days of symptom onset. Completion of the full 5-day treatment course is recommended even if the patient requires hospitalisation due to severe or critical COVID-19. In patients with moderate renal impairment, (eGFR ≥ 30 to < 60 mL/min) the dose of Paxlovid should be reduced to PF 07321332/ritonavir 150 mg/100 mg every 12 hours for 5 days. Paxlovid should not be used in patients with severe renal or severe hepatic impairment. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. Medicinal products that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening reactions, as well as medicinal product that are potent CYP3A inducers where significantly reduced plasma PF 07321332/ritonavir concentrations may be associated with the potential for loss of virologic response and possible resistance. Medicinal products listed below are a guide and not considered a comprehensive list of all possible medicinal products that are contraindicated with Paxlovid: *Alpha 1 adrenoreceptor antagonist:* alfuzosin; *Analgesics:* pethidine, piroxicam, propoxyphene; *Antianginal:* ranolazine; *Anticancer drugs:* neratinib, venetoclax; *Antiarrhythmics:* amiodarone, bepridil, dronedarone, encainide, flecainide, propafenone, quinidine; *Antibiotics:* fusidic acid, rifampicin; *Anticonvulsants:* carbamazepine, phenobarbital, phenytoin; *Anti-gout:* colchicine; *Antihistamines:* astemizole, terfenadine; *Antipsychotics/Neuroleptics:* lurasidone, pimozide, clozapine, quetiapine; *Ergot derivatives:* dihydroergotamine, ergonovine, ergotamine, methylergonovine; *GI motility agent:* cisapride; *Herbal products:* St. John's Wort (*Hypericum perforatum*); *Lipid-modifying agents:* lovastatin, simvastatin, lomitapide; *PDE5 inhibitors:* avanafil, sildenafil, vardenafil; *Sedative/Hypnotics:* clorazepate, diazepam, estazolam, flurazepam, oral midazolam, triazolam. **Warnings and Precautions:** *Risk of serious adverse reactions due to interactions with other medicinal products:* Due to effects on CYP3A metabolic pathways, potential for interactions should be considered with other medicinal products prior to and during Paxlovid therapy; concomitant medicinal products should be reviewed during Paxlovid therapy and the patient should be monitored for the adverse reactions associated with the concomitant medicinal products. The risk of interactions with concomitant medications during the 5-day treatment period for Paxlovid should be weighed against the risk of not receiving Paxlovid; please refer to Table 1 in SmPC section 4.5. *Severe renal impairment:* Paxlovid should not be used in patients with severe renal impairment (eGFR < 30 mL/min, including patients with ESRD under haemodialysis). *Severe hepatic impairment:* Paxlovid should not be used in patients with severe hepatic impairment. *Hepatotoxicity:* Caution should be exercised when administering Paxlovid to patients with pre existing liver diseases, liver enzyme abnormalities or hepatitis. *HIV resistance:* As PF-07321332 is coadministered with ritonavir, there may be a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection. *Excipients:* PF-07321332 tablets contain lactose, patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine. Contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. **Drug Interactions:** PF-07321332 and ritonavir are CYP3A substrates; therefore, medicinal products that induce CYP3A may decrease plasma concentrations and reduce therapeutic effect. Paxlovid (PF-07321332/ritonavir) is an inhibitor of CYP3A and may increase plasma concentrations of medicinal products that are primarily metabolised by CYP3A. Ritonavir has a high affinity for several cytochrome P450 (CYP) isoforms and may inhibit oxidation with the following ranked order: CYP3A4 > CYP2D6. Ritonavir also has a high affinity for P glycoprotein (P-gp) and may inhibit this transporter. Ritonavir may induce glucuronidation and oxidation by CYP1A2, CYP2C8, CYP2C9 and CYP2C19 thereby increasing the biotransformation of some medicinal products metabolised by these pathways. As a conservative measure, the drug-drug interactions pertaining to ritonavir used in chronic HIV infection should apply for Paxlovid. Medicinal products listed here are a guide and not considered a comprehensive list of all possible medicinal products that are contraindicated or may interact with PF-07321332/ritonavir: *Amphetamine derivatives:* amphetamine; *Analgesics:* buprenorphine, norbuprenorphine, fentanyl, methadone, morphine; *Antiarrhythmics:* digoxin; *Antiasthmatic:* theophylline; *Anticancer:* afatinib, abemaciclib, apalutamide, ceritinib, dasatinib, nilotinib, vincristine, vinblastine, encorafenib, fostamatinib, ibrutinib, venetoclax (contraindicated in some circumstances); *Anticoagulants:* rivaroxaban, vorapaxar, warfarin; *Anticonvulsants:* divalproex, lamotrigine, phenytoin; *Antidepressants:* amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline, desipramine; *Antihistamines:* fexofenadine, loratadine; *Anti-infectives:* rifabutin, voriconazole, ketoconazole, itraconazole, erythromycin, atovaquone, bedaquiline, delamanid, clarithromycin, sulfamethoxazole/trimethoprim; *Anti-HIV:* efavirenz, maraviroc, raltegravir, zidovudine; *Anti-HCV:* glecaprevir/pibrentasvir; *Antipsychotics:* haloperidol, risperidone, thioridazine; *β2-agonist (long acting):* salmeterol; *Calcium channel antagonist:* amlodipine, diltiazem, nifedipine; *Endothelin antagonists:* bosentan, riociguat; *HMG Co-A reductase:* atorvastatin, fluvastatin, pravastatin, rosuvastatin; *Hormonal contraceptive:* ethinyl estradiol; *Immunosuppressants:* cyclosporine, tacrolimus, everolimus; *PDE5 inhibitors:* sildenafil (contraindicated in some circumstances), tadalafil; *Sedatives/Hypnotics:* parenteral midazolam, alprazolam, buspirone; *Sleeping agent:* zolpidem; *Smoke cessation:* buproprion; *Steroids:* inhaled, injectable or intranasal fluticasone propionate, budesonide, triamcinolone, dexamethasone, prednisolone; *Thyroid hormone replacement therapy:* levothyroxine. Please refer to Table 1 in SmPC section 4.5 for additional information on interaction with medicinal products / other forms of interaction. **Fertility, pregnancy and lactation:** Women of childbearing potential should avoid becoming pregnant during treatment with Paxlovid and as a precautionary measure for 7 days after completing Paxlovid. Patients using combined hormonal contraceptives should be advised to use an effective alternative contraceptive method or an additional barrier method of contraception during treatment and until after one complete menstrual cycle after stopping Paxlovid. Paxlovid is not recommended during pregnancy and in women of childbearing potential not using contraception unless the clinical condition requires treatment with Paxlovid. Breast feeding should be discontinued during treatment with Paxlovid and as a precautionary measure for 7 days after completing Paxlovid. **Driving and operating machinery:** Paxlovid is expected to have no influence on the ability to drive and use machines. **Undesirable effects:** Common (≥ 1/100 to < 1/10) adverse events reported were dysgeusia, headache, diarrhoea and vomiting. See SmPC section 4.8 for full details.

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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.
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