

About your treatment with PAXLOVID[®] (nirmatrelvir/ritonavir) Patient Information Booklet

This booklet is intended only for use by patients in Great Britain who have been prescribed Paxlovid[®] for the treatment of mild-to-moderate COVID-19, who are at high risk for progression to severe COVID-19, including hospitalisation or death.

This booklet is not intended to replace the advice of your healthcare professional or to replace the advice in the Paxlovid Patient Information Leaflet, which is contained inside your medication package and should be consulted. If you have any questions about your medication, please speak to your doctor, nurse or pharmacist.

Please refer to the Paxlovid <u>Patient Information Leaflet</u> for detailed information about your medicine.

Paxlovid has a Conditional Marketing Authorisation in Great Britain. This means that there is more evidence to come about this medicine.

The MHRA - Medicines and Healthcare products Regulatory Agency - will review new information on this medicine at least every year and the Patient Information Leaflet will be updated as necessary.

> This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. This includes any possible side effects not listed in the package leaflet. If you get any side effects talk to your doctor, pharmacist or nurse. You can also report any side effects directly via the Coronavirus Yellow Card Reporting site <u>https://coronavirus-yellowcard.mhra.gov.uk</u> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.



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Introduction



Paxlovid is used in adults 18 years of age and older with mild-to-moderate COVID-19. It is only used in patients who are at high risk for progression to severe COVID-19, including hospitalisation or death.

You have been prescribed Paxlovid because you have tested positive for COVID-19, the disease caused by the SARS-CoV-2 virus, and you have been assessed as being at high risk of severe symptoms.

This booklet aims to cover key information you may find useful if you have been prescribed Paxlovid. It is intended to complement but not replace the information provided by your healthcare team.

This booklet is not intended to replace the Patient Information Leaflet which should be consulted. You can find this inside your medicine packet or [here].



Paxlovid is a combination of two active substances, nirmatrelvir and ritonavir. Nirmatrelvir is active against the virus that causes COVID-19 and stops it from multiplying in your body. This can help your body to overcome the virus infection, and may help you get better faster.

Ritonavir stops nirmatrelvir from being broken down in the body, so that nirmatrelvir can work for longer against the virus.



It is very important that you follow advice from your doctor or pharmacist about how to take Paxlovid and how to take your other medicines while taking Paxlovid.

Further information, with details on Paxlovid and how to take it, is available in the <u>Patient Information Leaflet</u> which should always be consulted.

COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2. Paxlovid Patient Information Leaflet. GB <u>https://www.medicines.org.uk/emc/files/pil.13145.pdf</u>. UK Health Security Agency. Guidance. Patient information for Paxlovid. Updated 4 May 2022. Available at: <u>https://</u> www.gov.uk/government/publications/covid-19-antiviral-treatment-paxlovid/patient-information-forpaxlovid. Accessed: October 2022.





What you need to know before you take Paxlovid

Do not take Paxlovid if:

- you have any allergies to the active ingredients (nirmatrelvir, ritonavir) or any of the other ingredients of Paxlovid (listed in section 6 of the Patient Information Leaflet)
- you have severe kidney disease or severe liver disease
- you are taking any medicines listed in section 2 of the <u>Patient Information Leaflet</u> as having the potential to cause serious or life-threatening side effects or affect how Paxlovid works

Warnings and precautions

• Paxlovid treatment may result in medicines used to treat HIV becoming less effective

Liver disease

• Tell your healthcare provider if you have or have had a liver disease; do not take Paxlovid if you have severe liver disease

Children and adolescents

• Do not give Paxlovid to children and adolescents under 18 years

Make sure that you follow the current UK government guidance on self-isolation and testing, since you have tested positive for COVID-19.

COVID-19, coronavirus disease 2019; HIV, human immunodeficiency virus. Paxlovid Patient Information Leaflet. GB <u>https://www.medicines.org.uk/emc/files/pil.13145.pdf</u>. UK Health Security Agency. Guidance. Patient information for Paxlovid. Updated 4 May 2022. Available at: <u>https://www.gov.uk/government/publications/covid-19-antiviral-treatment-paxlovid/patient-information-for-paxlovid</u>. Accessed: October 2022.



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What you need to know before you take Paxlovid (cont.)

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Other medicines and Paxlovid (see pg 6)

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including prescription and over-the-counter medicines, vitamins and herbal supplements
- Do not start taking a new medicine without telling your doctor; your doctor can tell you if it is appropriate to take Paxlovid with other medicines

Oral contraceptives

• Please tell your doctor if you are taking oral contraceptive pills as you may need to take extra contraceptive precautions such as using a condom

Pregnancy and breast-feeding (see pgs 10/11)

- Paxlovid is not recommended during pregnancy
- Breast-feeding is not recommended during treatment and for 7 days after the last dose of Paxlovid

Driving and using machines

• Paxlovid has not been specifically tested for its possible effects on the ability to drive a car or operate machines

Paxlovid contains lactose (a type of sugar)

 If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

Information on sodium content

• This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'

COVID-19, coronavirus disease 2019; HIV, human immunodeficiency virus. Paxlovid Patient Information Leaflet. GB <u>https://www.medicines.org.uk/emc/files/pil.13145.pdf</u>. UK Health Security Agency. Guidance. Patient information for Paxlovid. Updated 4 May 2022. Available at: <u>https://www.gov.uk/government/publications/covid-19-antiviral-treatment-paxlovid/patientinformation-for-paxlovid</u>. Accessed: October 2022.



If you are taking other medicines <> (

Many medicines interact with Paxlovid. If you are taking any other medicines, **please read the following carefully before taking Paxlovid.**

Taking Paxlovid at the same time as some other medicines may

- cause serious side effects
- stop Paxlovid from working properly
- stop some other medicines from working properly

Keep a list of your medicines to show your doctor and pharmacist. Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is appropriate to take Paxlovid with other medicines.

If you have forgotten to tell your doctor or pharmacist about one or more of the medicines you are taking, or if you have any questions, please contact your GP or call 119 for the NHS COVID-19 advice line.

Other medicines and medical devices include

Medicines prescribed by your GP practice or hospital

Medicines prescribed privately outside of the NHS

Any medicines bought from a pharmacy, shop or online without a prescription

Herbal remedies

Vitamin supplements

Medicines that come in patches, inhalers, suppositories, pessaries, lozenges, gels, drops, ointments or creams Read the Paxlovid Patient Information Leaflet carefully for more information about medicines that should not be taken with Paxlovid.

Please see the <u>Patient Information Leaflet</u> for more information on medicines that may not mix with Paxlovid.

GP, general practitioner; NHS, National Health Service. Paxlovid Patient Information Leaflet. GB <u>https://www.medicines.org.uk/emc/files/pil.13145.pdf</u>. UK Health Security Agency. Guidance. Patient information for Paxlovid. Updated 4 May 2022. Available at: https://www.gov.uk/government/publications/covid-19-antiviral-treatment-paxlovid/patientinformation-for-paxlovid. Accessed: October 2022.







Always take Paxlovid exactly as your doctor or pharmacist has told you. Check with them if you are not sure. Paxlovid contains two active ingredients (nirmatrelvir and ritonavir) that are packaged together.

Each Paxlovid dose consists of two tablets of nirmatrelvir (pink tablets) and one tablet of ritonavir (white tablet) that are taken together twice a day, for a total of 5 days.

Swallow the tablets whole, without chewing, breaking or crushing them.

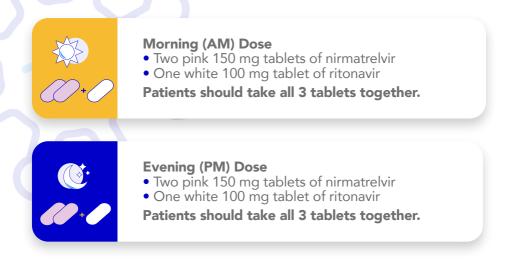
Paxlovid can be taken with or without meals.



A course of treatment lasts 5 days. Even if you feel better, do not stop taking Paxlovid without talking to your healthcare provider.

The blister foil for each day of treatment is divided into two different coloured sections – one for the morning (AM) dose and one for the evening (PM) dose.

The recommended dose of Paxlovid is 2 tablets of nirmatrelvir with 1 tablet of ritonavir by mouth twice daily.









Tell your doctor if you have moderate kidney disease because you will need an appropriate lower dose of Paxlovid. You should dispose of the unused tablets as advised by your pharmacist or doctor.

Do not take Paxlovid if you have severe liver or kidney disease.

If you forget to take a dose of Paxlovid take it as soon as you remember. If more than 8 hours have passed since your missed dose, then do not take the missed dose and just carry on as before.

Do not take a double dose to make up for a forgotten dose.



You must talk to a doctor if you do not feel better or if you feel worse while on treatment with Paxlovid.

If you take too much Paxlovid, call your healthcare provider or go to the nearest hospital straight away.

Paxlovid Patient Information Leaflet. GB <u>https://www.medicines.org.uk/emc/files/pil.13145.pdf</u>. UK Health Security Agency. Guidance. Patient information for Paxlovid. Updated 4 May 2022. Available at: <u>https://www.gov.uk/government/publications/covid-19-antiviral-treatment-paxlovid/patient-information-for-paxlovid</u>. Accessed: October 2022.





If you need to start, stop, or change medication



Tell your doctor or pharmacist that you are taking Paxlovid before:

- starting a new medicine
- stopping a medicine you are already taking
- changing the dose of a medicine you are already taking

Alternatively, call 119 for the NHS COVID-19 advice line.

UK Health Security Agency. Guidance. Patient information for Paxlovid. Updated 4 May 2022. Available at: <u>https://www.gov.uk/government/publications/covid-19-antiviral-treatment-paxlovid/patient-information-for-paxlovid</u>. Accessed: October 2022.





If you are or may become pregnant $\langle \rangle \equiv$

Paxlovid is not recommended during pregnancy because

- there is not enough information to be sure it is not harmful for pregnant patients
- it is not known if it will harm your baby while you are pregnant

Ask your doctor for advice if you are, think you may be, or are planning to get pregnant.

If you are taking Paxlovid and can become pregnant, you must use effective barrier contraception (e.g. condom, diaphragm or cap) or refrain from sexual activity for the duration of treatment and until after one full menstrual cycle is completed after stopping Paxlovid treatment.

Please tell your doctor if you are taking oral contraceptive pills as you may need to take extra contraceptive precautions such as using a condom.

> The <u>COVID-19 Antivirals Pregnancy Registry</u> is monitoring the safety of new COVID-19 antivirals when taken in or around pregnancy.

Please note: this is a link is to a third-party-website (outside of Pfizer). Links to external websites are provided as a resource to the reader. This website is neither owned or controlled by Pfizer Ltd. Pfizer accepts no responsibility for the content or services of the linked site.

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If you find out you are pregnant, or became pregnant while taking Paxlovid, or shortly after, report this by contacting the UK COVID-19 Antivirals in Pregnancy Registry on 0344 892 0909 or by asking your doctor or your partner to do this on your behalf.

COVID-19, coronavirus disease 2019.

Paxlovid Patient Information Leaflet. GB <u>https://www.medicines.org.uk/emc/files/pil.13145.pdf</u>. UK Health Security Agency. Guidance. Patient information for Paxlovid. Updated 4 May 2022. Available at: <u>https://www.gov.uk/government/publications/covid-19-antiviral-treatment-paxlovid/patient-information-for-paxlovid</u>. Accessed: October 2022.



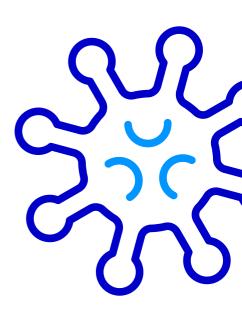




If you are breast-feeding or are planning to breastfeed, tell your doctor before taking this medicine.

It is not known if Paxlovid gets into breast milk and will be passed to the baby.

Breastfeeding is not recommended during treatment with Paxlovid and for 7 days after the last Paxlovid dose.



Paxlovid Patient Information Leaflet. GB <u>https://www.medicines.org.uk/emc/files/pil.13145.pdf</u>.







Like all medicines, Paxlovid can cause side effects, although not everybody gets them. Paxlovid is still being studied, so it is possible that all of the risks are not known at this time.

If you get any side effects, talk to your doctor or pharmacist.

Common side effects that may affect up to 1 in 10 people are:

- altered sense of taste
- diarrhoea
- vomiting

For more information about the possible side effects when taking Paxlovid, read the <u>Patient Information Leaflet</u>.

Reporting side effects

If you get any side effects talk to your doctor, pharmacist or nurse. You can also report any side effects directly via the Coronavirus Yellow Card Reporting site <u>https://coronavirus-yellowcard.mhra.</u> <u>gov.uk</u> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

MHRA, Medicines and Healthcare products Regulatory Agency. Paxlovid Patient Information Leaflet. GB <u>https://www.medicines.org.uk/emc/files/pil.13145.pdf</u>. UK Health Security Agency. Guidance. Patient information for Paxlovid. Updated 4 May 2022. Available at: <u>https://www.gov.uk/government/publications/covid-19-antiviral-treatment-paxlovid/patient-information-for-paxlovid</u>. Accessed: October 2022.



