

## Information Note - Access to COVID-19 Therapeutics

### Background

Infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and illness with the associated coronavirus disease 2019 (COVID-19) continue to threaten [global health](#). Some of this tragedy could have been [averted](#) with the development of deliverable, orally bioavailable, direct-acting antiviral therapeutics.

Treatment of mild-to-moderate COVID-19 has now become more accessible to vulnerable people who need it most. **Nirmatrelvir + Ritonavir** along with Molnupiravir, are the first oral anti-viral treatments for COVID-19 that were recently granted Emergency Use Authorisation (EUA) by various Stringent Regulatory Authorities ([SRA](#)). These oral antivirals are an at-home COVID-19 treatment option for those who are high risk of severe illness. The [oral route](#) of delivery makes it convenient to take at home, unlike some other drugs for covid-19, which require intravenous infusion.

On 22<sup>nd</sup> April 2022, [WHO made a strong recommendation](#) for the use of **Nirmatrelvir-Ritonavir** in patients (adults) with non-severe illness at the highest risk of hospitalization (excluding pregnant women, children, or those with possible dangerous drug interactions as many drugs interact with nirmatrelvir-ritonavir). Nirmatrelvir + Ritonavir is [not recommended in patients with non-severe illness at a low risk of hospitalization](#).

**Nirmatrelvir + Ritonavir** [reduced risk](#) of [hospitalization](#) or death from any cause by [89%](#) (within three days of symptom onset) and [88%](#) (within five days of symptom onset) compared to placebo, with no deaths observed in the treatment group.

Also on 22<sup>nd</sup> April 2022, WHO made a conditional recommendation for use of [Remdesivir](#) Injections and on 3<sup>rd</sup> March 2022, for use of [Molnupiravir](#) for patients with non-severe COVID-19 at highest risk of hospitalization. Earlier other COVID-19 therapeutics like Dexamethasone, Baricitinib, Tocilizumab have also been recommended by [WHO](#).

UNICEF will continuously strive to offer them when available & accessible, this information note will be updated on continuous basis.


### Purpose

The purpose of this bulletin is to provide information on access to COVID-19 therapeutics available from UNICEF SD.

### Product Range

To support expanded access to low- and middle-income countries and ensure early access, UNICEF has following products in its portfolio,

### Nirmatrelvir 150mg tablets, co-packaged with Ritonavir 100 mg tablets

Material Number	Material Description
<p><b>S0004214</b></p>  <p>The pack image is for illustration purpose only. Actual supplied product pack might be different.</p>	<p><b>Nirmatrelvir150+RTV100mg tab/4+2/PAC-5</b></p> <p>Each co-packaged blister card/strip contains, 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each) and indicates which tablets need to be taken in the morning and evening.  <b>Packing:</b> Each carton pack contains 5 daily-dose blister cards with a total of 30 tablets (i.e. 20 Nirmatrelvir 150 mg tablets and 10 Ritonavir 100 mg tablets).</p> <p>Please refer : <a href="https://supply.unicef.org/s0004214.html">https://supply.unicef.org/s0004214.html</a></p> <p><b>Packaging language text:</b> English  <b>Weight and volume of each carton pack of 30 tablets:</b>  Gross weight (Approx.): 0,05 kg; Gross volume (Approx.): 0,000356 m3  Dimension: 60 mm x 110 mm x 54 mm</p>

**Product pack Details– Nirmatrelvir/ Ritonavir tablets.**

Currently UNICEF SD will be supplying Nirmatrelvir 150 mg tablets /Ritonavir 100 mg tablets, co-packaged for oral use



Each carton pack contains 5 daily-dose blister cards with a total of 30 tablets packaged in a carton.

Each daily blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each) and indicates which tablets need to be taken in the morning and evening.

Patient need to take all 3 tablets as indicated on the foil in the morning (AM dose) and all 3 tablets in the evening (PM Dose). Please make sure that you take the medication as instructed by your doctor or a healthcare professional.

**Caution & Warning:**

**This medicine has been given “Emergency Use Authorisation” or ‘conditional approval’.** This means that there is more evidence to come about this medicine. Many medicines interact with Nirmatrelvir - Ritonavir 100 mg tablets and has risk of serious Adverse Reactions due to drug Interaction. In any patient being considered for nirmatrelvir-ritonavir use, clinicians need to give serious consideration to drug interactions. [The Liverpool COVID-19 drug interaction checker](#) may be useful in this regard. Patients should keep a list of their medicines to show to the doctor and pharmacist. **Doctor can only recommend if it is safe to take Nirmatrelvir 150mg tablets+ Ritonavir 100 mg tablets with other medicines.**

**Target Audience:**

For Adult patients with [non-severe COVID-19 at highest risk of hospitalization](#).

Non-hospitalized, high-risk adult COVID-19 patients, with [laboratory-confirmed diagnosis](#) of mild to moderate SARS-CoV-2 infection within a five-day period and having at least one characteristic or underlying medical condition associated with an increased risk of developing severe illness from COVID-19 and who do not require supplemental oxygen.

**Therapeutic Indications:**

[Indicated](#) for the treatment of COVID-19 in Adult patients with non-severe COVID-19 at highest risk of hospitalization (i.e. adult patients who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19).

Nirmatrelvir + Ritonavir is **not recommended or indicated in patients with non-severe illness at a low risk of hospitalization.**

And also not indicated in children, breastfeeding or pregnant women with COVID-19.

**[Route, dosage and duration:](#)**

- The recommended dose for nirmatrelvir-ritonavir is 300 mg (two 150 mg tablets) of nirmatrelvir and 100 mg (one 100 mg tablet) of ritonavir every 12 hours daily for 5 days.
- In renal insufficiency (GFR 30–59 mL/min) the dose reduction is 150 mg of nirmatrelvir and 100 mg of ritonavir every 12 hours daily for 5 days.
- Administration should be as early as possible in the time course of the disease. As per clinical studies, nirmatrelvir-ritonavir should be administered within 5 days of disease onset.
- Nirmatrelvir-ritonavir tablets should not be offered to children, breastfeeding or pregnant women with COVID-19.
- Tablets can be taken with or without food. The tablets should be swallowed whole and not chewed, broken or crushed.

**[Number of Nirmatrelvir + Ritonavir tablets required by each patient:](#)**

**Each patient will require 30 tablets (20 Nirmatrelvir 150mg tablets, and 10 Ritonavir 100 mg tablets) for 5 days treatment** i.e., one carton pack contains 5 daily-dose blister cards with a total of 30 tablets packaged in a carton.

Each daily blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each) and indicates which tablets need to be taken in the morning and evening.


Each dose consists of 2 tablets of nirmatrelvir and 1 tablet of ritonavir, which are taken together twice a day (morning & evening), for a total of 5 days.

## How to Access to Nirmatrelvir 150mg tablets, co-packaged with Ritonavir 100 mg tablets from UNICEF Supply Division

All enquiries and requests for Nirmatrelvir 150mg tablets, co-packaged with Ritonavir 100 mg tablets supply should be addressed to [psid@unicef.org](mailto:psid@unicef.org)

## Other COVID-19 therapeutics available from UNICEF SD

### Molnupiravir 200 mg Capsules

<b>Material Number</b>	<b>Material Description</b>
S0004215 	<p><b>Molnupiravir 200mg caps/PAC-40</b></p> <p>Each capsule contains: Molnupiravir 200mg.</p> <p><b>Packing:</b> HDPE bottle of 40 capsules. Please refer, <a href="https://supply.unicef.org/s0004215.html">https://supply.unicef.org/s0004215.html</a></p> <p><b>Packaging language text:</b> English <b>Weight and volume of each HDPE bottle (40 capsules):</b> Gross weight (Approx.): 0,05 kg; Gross volume (Approx.): 0,00047 m3</p>

#### Target Audience:

For patients with non-severe COVID-19 who are at highest risk of hospitalization (excluding pregnant, breastfeeding and children). Typical characteristics of people at highest risk include those with older age, immunodeficiencies and/or chronic diseases (e.g., diabetes) and lack of COVID-19 vaccination.

#### Therapeutic Indications:

Adult patients with confirmed (NAAT/PCR or antigen-detection test) non-severe COVID-19 **who are > 18 years of age**, non-pregnant, and are at highest risk for hospitalization, with symptoms less than 5 days, for whom alternative treatment options are not accessible or clinically appropriate.

Those at **highest risk** for disease progression typically are:

- older age (> 60 years);
- have immunosuppression and/or chronic disease;
- unvaccinated against COVID-19.

**Immunosuppression and chronic diseases such as:** hypertension, diabetes, cardiac disease, chronic lung disease, cerebrovascular disease, dementia, mental disorders, chronic kidney disease, immunosuppression (including HIV), obesity, cancer.

**Route, dosage and duration: Adults :** Under the care of a health care provider, [Molnupiravir, an oral capsule, is given as four capsules \(total 800 mg\) twice daily for five days; within 5 days of symptom onset](#). To be used as early as possible after infection, it can help prevent hospitalization.

#### Number of Molnupiravir capsules required by each patient:

Each patient will require 40 capsules of Molnupiravir 200 mg. i.e., one HDPE bottle or blister pack containing 40 capsules. (Number of capsules per patient calculation: Each adult patient would require 8 capsules of 200 mg (i.e., 800 mg) per day for 5 days i.e., 40 capsules (of 200 mg) in total for the full treatment course.

#### How to Access to Molnupiravir capsules from UNICEF Supply Division

All enquiries and requests for molnupiravir 200mg supply should be addressed to [psid@unicef.org](mailto:psid@unicef.org)

## Additional Information on Molnupiravir- Precautions / Warnings

- The longer-term harms of Molnupiravir remain unknown in the absence of clinical evidence, both for individual patients and at population level. These include genotoxicity, emergence of resistance, and emergence of [new variants](#).
- The conditional recommendation reflects the concern for widespread treatment with Molnupiravir [before more safety data become available](#).
- Use of Molnupiravir should be accompanied [by mitigation strategies](#) such as avoiding the drug in younger adults, active pharmacovigilance programmes, and monitoring viral polymerase and spike sequences.
- [Alternative effective treatments with different](#) safety profiles recommended by WHO, such as neutralizing monoclonal antibodies, like sotrovimab, may be preferable or antivirals if available.
- **Paediatric population/ Children & Adolescents (below 18 years)** : Molnupiravir is [not recommended](#) for children below 18 years.
- **Pregnancy or women of childbearing potential:** Molnupiravir [not recommended](#) during pregnancy.
- **Breast-feeding** : Breast-feeding is [not recommended](#) during treatment and for 4 days after the last dose of Molnupiravir.
- **Contraception:**  
**Females:** Women of childbearing potential should use effective contraception for the duration of treatment and for 4 days after the last dose of Molnupiravir.  
**Males:** should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose of Molnupiravir.

## Dexamethasone Tablets & Injections

Earlier in Sept 2020, [WHO](#) had **made a strong recommendation** for use of systemic (i.e., intravenous or oral) corticosteroid therapy (e.g. Dexamethasone) in patients with severe and critical COVID-19.

Please refer to the following link for more information on Dexamethasone tablets & Injections available from UNICEF SD [Information on Pharmaceutical Products for Management of COVID-19](#)

### Guideline for Use:

[Therapeutics and COVID-19: living guideline](#)

[Practical information: molnupiravir](#)

[Practical Information Nirmatrelvir/Ritonavir](#) [Nirmatrelvir-ritonavir for COVID-19](#) [Administration of Nirmatrelvir/ritonavir for COVID-19](#) [Safety and monitoring for patients receiving Nirmatrelvir-ritonavir for COVID-19](#)

### Reporting of adverse events for all COVID-19 therapeutics:

Advise patients to enrol and report adverse events to local or national pharmacovigilance programmes. These are intended to recognize side-effects and potential harms not detected in clinical trials.

## COVID-19 in vitro diagnostics

For information on the global availability of COVID-19 diagnostics for low- and middle-income countries, please refer to [COVID-19 in vitro diagnostics supply assessment and outlook update | UNICEF Supply Division](#)

**DISCLAIMER:** *This technical bulletin does not provide medical advice. The information, including but not limited to, text, graphics, images and other material contained in this technical bulletin is for informational purposes only. The purpose of this technical bulletin is to inform about products that are available for supply via UNICEF Supply Division. It is not intended to be a substitute for professional medical advice, diagnosis or treatment.*

### For more information contact:

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