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Information Note - Access to COVID-19 Therapeutics

unicef for every child

Supply Division, Copenhagen

Background

The Covid-19 pandemic has resulted in substantial global morbidity and mortality as well as disruption of the economies of virtually every country. 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. Molnupiravir and nirmatrelvir + ritonavir, are the first oral anti-viral treatments for COVID-19 that were recently granted Emergency Use Authorization (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.

On 3rd March 2022, WHO made a conditional recommendation for the use of Molnupiravir in adults with for patients with non-severe COVID-19 who are at highest risk of hospitalization (excluding pregnant, breastfeeding and children).

Molnupiravir is typically for people who have not received a COVID-19 vaccination, older people, people with immunodeficiencies and people living with chronic diseases.

As this is a new medicine, there is little safety data. WHO recommends active monitoring for drug safety, along with other strategies to mitigate potential harms. Children, and pregnant and breastfeeding women should not be given the drug. People who take Molnupiravir should have a contraceptive plan, and health systems should ensure access to pregnancy testing and contraceptives at the point of care.

Early treatment with Molnupiravir reduced the risk of hospitalization or death in at-risk, unvaccinated adults with Covid-19.

Earlier other COVID-19 therapeutics like Dexamethasone, Baricitinib, Sotrovimab, 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,

Molnupiravir 200 mg Capsules

Material Number	*Material Description*
S1521034 	**Molnupiravir 200mg caps/PAC-40** Each capsule contains: Molnupiravir 200mg. **Packing:** HDPE bottle of 40 capsules. Please refer, https://supply.unicef.org/s1521034.html **Packaging language text**: English **Weight and volume of each HDPE bottle (40 capsules):** Gross weight (Approx.): 0,05 kg; Gross volume (Approx.): 0,00047 m3

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 capsules required by each patient:
Each patient will require 40 capsules of Molnupiravir 200 mg. i.e., one HDPE bottle 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

Additional Information on Molnupiravir

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.

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

Other COVID-19 therapeutics available from UNICEF SD

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

For more information contact:

UNICEF Supply Division, Medicines & Nutrition Centre at rkshirsagar@unicef.org

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