



**KEMENTERIAN KESIHATAN MALAYSIA**

*Ministry of Health Malaysia*

**Bahagian Amalan & Perkembangan Farmasi**

*Pharmacy Practice & Development Division*

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Ruj Kami : KKM.600-34/11/24JLD4(81)  
Tarikh : 22 Ogos 2022

**SEPERTI SENARAI EDARAN**

YBhg. Datuk/Datin/Dr./Tuan/Puan,

**PEMAKLUMAN KEMAS KINI DATA KESTABILAN UBAT ANTIVIRAL  
PAXLOVID® JIKA BERLAKU PENYIMPANGAN SUHU**

Saya dengan segala hormatnya merujuk perkara tersebut di atas.

2. Dimaklumkan bahawa terdapat maklumat terkini daripada Pfizer (Malaysia) Sdn. Bhd. berkaitan kestabilan ubat Paxlovid® sekiranya berlaku penyimpangan suhu semasa pengendalian atau penyimpanan ubat ini seperti di **Lampiran A**. Walaubagaimanapun, semua fasiliti kesihatan diingatkan bahawa suhu penyimpanan bagi ubat ini adalah di bawah suhu 25°C dan tidak boleh simpan di peti sejuk atau peti beku seperti yang dinyatakan dalam *prescribing information*.

3. Data kestabilan ini akan dikemas kini dari semasa ke semasa oleh Pfizer (Malaysia) Sdn. Bhd. Maklumat ini hanya menjadi rujukan jika berlaku penyimpangan suhu semasa pengendalian stok Paxlovid®. Sekiranya terdapat sebarang ketidakpastian tentang kestabilan ubat ini, sila hubungi [medical.query@pfizer.com](mailto:medical.query@pfizer.com).

Sekian, terima kasih

**"WAWASAN KEMAKMURAN BERSAMA 2030"**

**"BERKHIDMAT UNTUK NEGARA"**

Saya yang menjalankan amanah,

**(FUZIAH BINTI ABDUL RASHID) RPh : 1359**

Pengarah

Bahagian Amalan & Perkembangan Farmasi

Kementerian Kesihatan Malaysia

NHT/NAA/otc

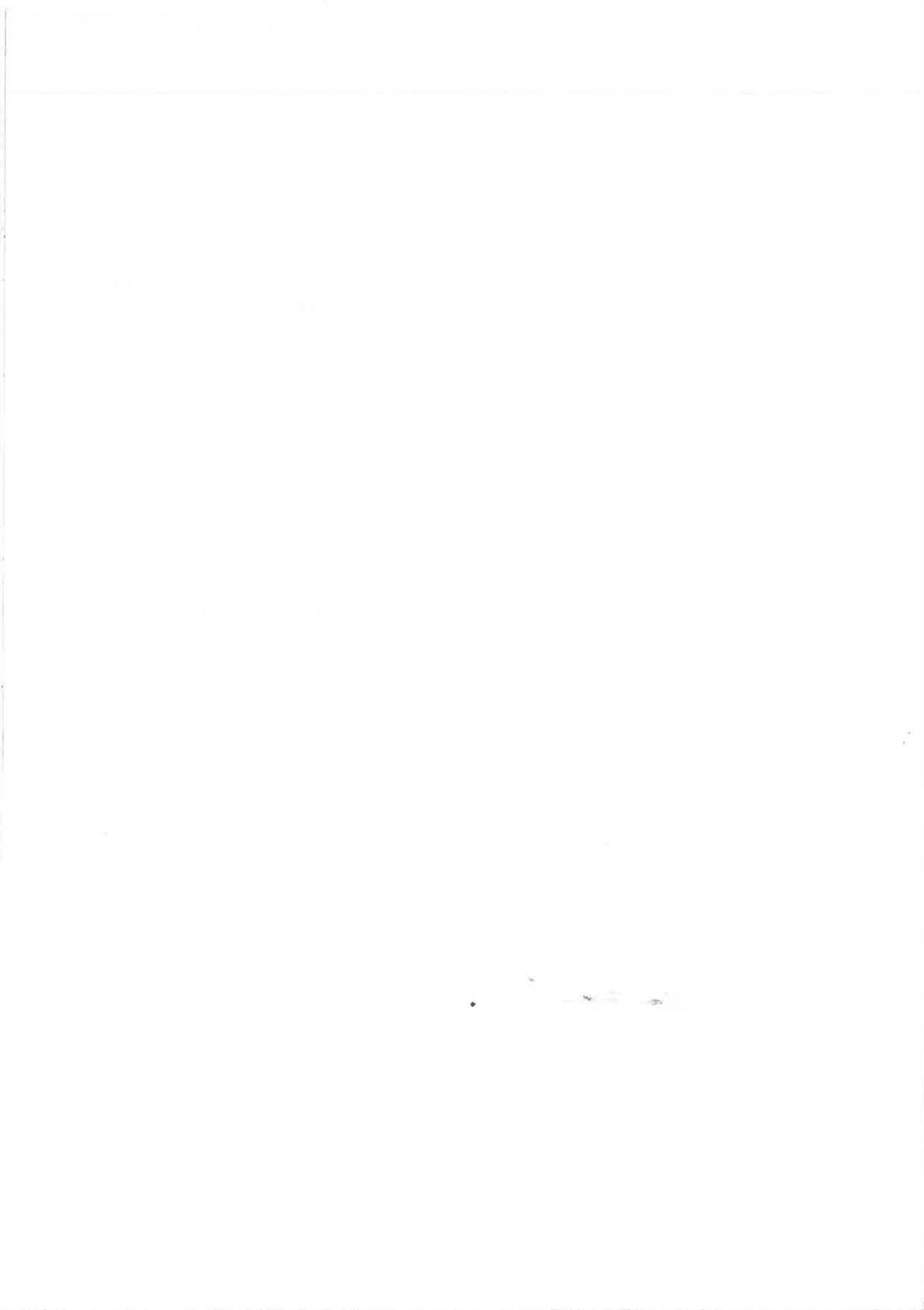
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CERTIFIED TO ISO 9001:2015  
CERT. NO : QMS 01408



**SK**

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**SENARAI EDARAN**

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Timbalan Pengarah Kesihatan Negeri (Farmasi),  
Jabatan Kesihatan Negeri Perlis

Setiausaha Kehormat  
Persatuan Perubatan Malaysia  
(*Malaysia Medical Association, MMA*)

Presiden  
*Medical Practitioners Coalition Association of Malaysia (MPCAM)*

Presiden  
Persatuan Doktor-Doktor Islam Malaysian (PERDIM)

Presiden  
*Federation of Private Medical Practitioners' Association of Malaysia (FPMPAM)*

Presiden  
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Pengarah  
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16-August-2022

otcmy@moh.gov.my

**MEDICAL INFORMATION 00736153 PAXLOVID (PF-07321332/ ritonavir)**

Dear Ms. Tuan Chin Ong

This letter is in response to your inquiry regarding PAXLOVID (PF-07321332/ ritonavir).

If you did not specifically request this information, please email [medical.query@pfizer.com](mailto:medical.query@pfizer.com) to report this to us.

Please find attached a document titled "Paxlovid - Stability Above Recommended Storage Temperatures", which was last updated on June 13, 2022, as requested.

**Prescribing Information**

Please review the full Product Information (PI) of our medicines for a complete list of important treatment considerations regarding box warning (if applicable), indications, dosage & administration, contraindications, warnings & precautions, interactions and adverse effects.

It is not recommended to use our medicines in any manner other than as described in their respective PIs.

We hope that the information provided is useful to you. Should you need further clarification, please do not hesitate to contact Pfizer Medical Information.

The reference number for your enquiry is 00736153.

Sincerely



Pfizer Medical Information

*This information is supplied as a professional courtesy in response to your inquiry. It is intended to provide pertinent data to assist you in forming your own conclusions and making decisions. The information is not intended to advocate any indication, dosage or other claim that is not covered in the product prescribing information.*

**Privacy Notice**

"Pfizer stores your personal information (such as name, e-mail and contact number, including any sensitive personal information pertaining to your physical or mental health or condition, which you have provided to us to enable us to address your enquiry, complaint or other matters that you have raised, and to document our response. Your information will only be used for this purpose, unless required for legal proceedings. If reporting an adverse event, the information provided will be used in order to meet our regulatory requirements relating to the safety of our medicines. It may be necessary to share your personal information with Pfizer affiliates, partners, service providers, vendors and regulatory authorities located both within and outside of your home country. In accordance with applicable law, you may have a right to access, correct and limit our processing of your information. For any questions regarding our use of your personal information please contact Pfizer's Privacy Officer by using the local Pfizer telephone number +603-22816000 or by e-mail [malaysia\\_privacy.officer@pfizer.com](mailto:malaysia_privacy.officer@pfizer.com). Please note that it will be necessary for Pfizer to process your personal information for the purposes stated above, without which we may not be able to take all necessary measures to address or rectify the adverse event and/or medical query in question."

**Privacy Notice***Malay version*

Pfizer menyimpan maklumat peribadi (seperti nama, e-mel dan nombor telefon, termasuk data peribadi sensitif mengenai kesihatan atau keadaan fizikal, yang telah diberikan oleh anda untuk membolehkan kami menjawab kepada pertanyaan, aduan atau perkara-perkara lain yang telah ditujukan oleh anda, dan juga untuk mendokumentasikan jawapan kami. Maklumat anda hanya akan digunakan untuk tujuan-tujuan ini, melainkan jika diperlukan untuk prosiding-prosiding perundangan. Jika melaporkan peristiwa buruk, maklumat yang diberikan akan digunakan untuk mematuhi keperluan-keperluan pengawalseliaan kami yang berkaitan dengan keselamatan ubat-ubatan kami. Ia mungkin diperlukan untuk berkongsi maklumat peribadi anda kepada anggota-anggota gabungan Pfizer, rakan-rakan kongsi Pfizer, pembekal-pembekal perkhidmatan, vendor-vendor dan pihak-pihak berkuasa yang terletak di dalam dan ataupun di luar negara asal anda. Selaras dengan undang-undang yang terpakai, anda berhak untuk mengakses, membetulkan dan mengehadkan pemprosesan maklumat anda oleh kami. Untuk apa-apa persoalan mengenai penggunaan maklumat peribadi anda oleh kami, sila hubungi Pegawai Privasi Pfizer melalui telefon nombor Pfizer tempatan +603-22816000, atau melalui emel: [malaysia\\_privacy.officer@pfizer.com](mailto:malaysia_privacy.officer@pfizer.com). Sila ambil perhatian bahawa ia adalah perlu untuk Pfizer memproses maklumat peribadi anda untuk tujuan-tujuan yang dinyatakan di atas, di mana tanpanya kami mungkin tidak dapat mengambil semua langkah yang diperlukan untuk menangani atau membetulkan peristiwa buruk dan/atau pertanyaan perubatan yang berkenaan.

## **PAXLOVID™ (PF-07321332 (nirmatrelvir); ritonavir) Stability Above Recommended Storage Temperatures**

A Conditional Registration of Pharmaceutical Products during Disaster has been granted in Malaysia for the product PAXLOVID™ (PF-07321332 150mg film-coated tablets and ritonavir 100mg film-coated tablets) 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.

This letter regarding PAXLOVID™ (PF-07321332 150mg film-coated tablets and ritonavir 100mg film-coated tablets) includes information that is inconsistent with the product uses described in the Prescribing Information. Pfizer does not recommend the use of PAXLOVID™ (PF-07321332 150mg film-coated tablets and ritonavir 100mg film-coated tablets) outside the information contained in the Prescribing Information.

This document was last updated on June 13, 2022. Please refer to this document for the specific temperature excursion you are inquiring about.

Note that the stability information can be updated; therefore, we recommend that you contact Pfizer Medical Information following future temperature excursions from the recommended storage conditions to ensure you have the most up to date information on this topic.

If the specific temperature excursion you are inquiring about is not supported by the data provided below, please contact Pfizer Medical Information directly via [this link](#).

### **SELECT PRESCRIBING INFORMATION**

Paxlovid tablets are recommended to be stored below 25°C.<sup>1</sup>

Do not refrigerate or freeze.<sup>1</sup>

PF-07321332 (nirmatrelvir); ritonavir is not approved for use after being stored in any manner other than as described in the Prescribing Information. Pfizer does not suggest or recommend its use in this manner.

For further information regarding indications, dosage & administration, contraindications, warnings & precautions, interactions, and adverse effects, please refer to the full Prescribing Information for PF-07321332 (nirmatrelvir); ritonavir

### **ADDITIONAL STABILITY INFORMATION**

Pfizer has additional stability data for PF-07321332 (nirmatrelvir); ritonavir exposed to temperatures other than the ones recommended in the Prescribing Information. Storage of PF-07321332 (nirmatrelvir); ritonavir for the specified temperatures and periods provided below is not expected to compromise product quality attributes or container integrity:<sup>2</sup>

25°C to 30°C (77°F to 86°F): 3 months

30°C to 40°C (86°F to 104°F): 2 weeks

40°C to 50°C (104°F to 122°F): 5 days

Pfizer has no data to share for PF-07321332 (nirmatrelvir); ritonavir stored at temperatures > 50°C ± 2°C (More than 122°F).<sup>2</sup>

Packaged product that has experienced a temperature excursion can be placed back at the recommended storage conditions according to the Prescribing Information and used for their full labeled storage periods as long as the total time at any temperature range has not been exceeded.<sup>2</sup>



Healthcare Professionals (HCPs) should consider those data, including its limitations, in determining whether Paxlovid exposed to temperatures outside of the recommended storage and handling conditions remain suitable for patient use. It is the responsibility of the HCP to evaluate these data in the context of the actual temperature excursion and the duration of excursion that occurred. Pfizer is unable to make any treatment recommendations for individual patients.

Please note that we do not provide external, non-Pfizer published data (e.g., in Handbook of Injectable Drugs, Micromedex or published articles) on off-label stability of PF-07321332 (nirmatrelvir); ritonavir because the products, formulations or test methods may not be applicable to PF-07321332 (nirmatrelvir); ritonavir, as marketed by Pfizer.

Please take note product specifications and manufacturing standards may change over time. As such, previously provided information may require updating.

#### REFERENCES

- 1 Paxlovid™ (PF-07321332; ritonavir) film-coated tablets. Package Insert. Pfizer Malaysia
- 2 PF-07321332; ritonavir Data on File 123 Pfizer.