

PT. Pfizer Indonesia
World Trade Center 3, 28th Floor
Jl. Jend. Sudirman Kav. 29 – 31
Jakarta 12920, Indonesia



No. 393/RA/EA/XII/2022

Jakarta, 16 Desember 2022

Yth.
Tenaga Kesehatan

Perihal: Informasi mengenai EUA Paxlovid 150/100 mg Film-coated Tablet

Dengan hormat,

Sehubungan dengan persetujuan EUA Paxlovid 150/100 mg Film-coated Tablet yang telah kami terima dari Badan POM, berikut kami sampaikan beberapa informasi terkait produk Paxlovid yang dipasok ke Indonesia **saat ini**:

1. Deskripsi Produk

Nama Produk	: Paxlovid
Zat Aktif	: Tiap tablet salut selaput mengandung: Nirmatrelvir 150 mg Tiap tablet salut selaput mengandung: Ritonavir 100 mg
Kemasan	: Dus, 5 blister @ 4 tablet salut selaput Nirmatrelvir 150 mg dan 2 tablet salut selaput Ritonavir 100 mg
Pendaftar	: PT. Pfizer Indonesia, Jakarta
Produsen	: <u>Tablet Nirmatrelvir 150 mg diproduksi oleh:</u> Pfizer Manufacturing Deutschland GmbH ,Freiburg, Germany <u>Tablet Ritonavir 100 mg diproduksi oleh:</u> Hetero Labs Limited, Telangana, India <u>Kemasan kombipak</u> Diproduksi oleh: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany Dikemas dan dirilis oleh: Pfizer Italia S.r.l., Ascoli Piceno, Italy
No EUA	: EUA2254201117A1
Penyimpanan	: Store below 25°C
Masa Simpan	: 12 bulan
No Batch	: GR8379
Tanggal Produksi	: Oct 2022
Tanggal Kadaluarsa	: Sep 2023

2. Kemasan produk Paxlovid yang digunakan merupakan Pfizer Global Pack. Saat ini belum tersedia kemasan produk dengan persyaratan country-specific.
3. QR Code dicetak pada kemasan dus yang selanjutnya dapat digunakan oleh Tenaga Kesehatan untuk mengakses Factsheet Paxlovid yang telah disetujui Badan POM dengan cara memindai QR Code.
4. PT Pfizer Indonesia akan menginformasikan lebih lanjut jika terdapat pembaharuan informasi di kemudian hari.

PT. Pfizer Indonesia

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Jakarta 12920, Indonesia



Demikian informasi ini kami sampaikan. Atas perhatian Ibu/Bapak, kami ucapkan terima kasih.

Hormat kami,

R. Iin Nurhayati

R. Iin Nurhayati

18 Dec 2022 20:17:027-0500

REASON: I approve this document.

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R. Iin Nurhayati

Head of Regulatory Affairs, Pfizer Indonesia

EA

Biopharmaceuticals Group

Emerging Markets



Validation Report

1 

Subject CN	TAIGLE LLC
Subject DN	EMAILADDRESS=operations@msbdocs.com,CN=TAIGLE LLC,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email	operations@msbdocs.com
Serial #	13237844152787342823059737218626799146
Issuer DN	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
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Audit Trail Report

Document Name: Update EUA Paxlovid DHCP letter for fact sheet bundling FB-AS.pdf

Document ID: 7b22be29-4de1-4116-8433-1e2db8b65b40

Time Stamp	User	Action	Details
16 Dec 2022 10:45:018-0500	Elis Apriyanti UUID : bc2371c4-2e2f-49c2-a88e-2f8e9e0a6855 Email : elis.apriyanti@pfizer.com IP Address : 204.114.196.5	Started	The custodian composed the ePak succesfully. Subject: Update EUA Paxlovid DHCP letter for fact sheet bundling FB-AS ePak UUID: 4667f003-69b5-4ba3-b033-af2b47dc9007
16 Dec 2022 10:45:018-0500	R. lin Nurhayati UUID : 7949d5c6-de42-450d-a3b3-abafd7ef3236 Email : r.iin.nurhayati@pfizer.com	RequestSent	Sign request sent to ePak recipient.
16 Dec 2022 10:45:018-0500	Elis Apriyanti UUID : bc2371c4-2e2f-49c2-a88e-2f8e9e0a6855 Email : elis.apriyanti@pfizer.com	RequestSent	Sign request sent to ePak recipient.
16 Dec 2022 10:45:021-0500	Elis Apriyanti UUID : bc2371c4-2e2f-49c2-a88e-2f8e9e0a6855 Email : elis.apriyanti@pfizer.com IP Address : 204.114.196.5	DocumentViewed	Document viewed by signer.
16 Dec 2022 10:45:047-0500	Elis Apriyanti UUID : bc2371c4-2e2f-49c2-a88e-2f8e9e0a6855 Email : elis.apriyanti@pfizer.com IP Address : 204.114.196.5	SignerTagFilled	The signer filled Initials. Value: true
18 Dec 2022 20:16:013-0500	R. lin Nurhayati UUID : 7949d5c6-de42-450d-a3b3-abafd7ef3236 Email : r.iin.nurhayati@pfizer.com IP Address : 204.114.196.5	DocumentViewed	Document viewed by signer.
18 Dec 2022 20:17:027-0500	R. lin Nurhayati UUID : 7949d5c6-de42-450d-a3b3-abafd7ef3236 Email : r.iin.nurhayati@pfizer.com IP Address : 204.114.196.5	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document. Consent: I understand that my Electronic Signature is Equivalent to my Handwritten Signature and is therefore legally binding. My Electronic Signature will remain unique to me, and under no circumstance I am allowed to disclose my password to any individual which may allow unauthorized access to system. I understand that I am accountable and responsible for all actions associated with my Electronic Signature.
18 Dec 2022 20:17:027-0500	Elis Apriyanti UUID : bc2371c4-2e2f-49c2-a88e-2f8e9e0a6855 Email : elis.apriyanti@pfizer.com	Completed	The ePak is completed successfully.