

*** LABEL APPROVAL ***

Study: MV45225

Booklet Front Page

Report language: English

Template Name: 45225_BALO_20_BX_BFP

Gen.Var.Des.: BFP6 40x100 BALO 2FC 20MG BX wL MV45225

Gen.Variant: 45225_BFP1

Master Label Document:

Created by PTDS Global Clinical Label Coordination

Generation date: NOV/07/2023

Following section is relevant for approval:

MV45225 / RECOVERY
Blister with 2 film-coated
tablets baloxavir marboxil
20 mg
(1) Batch no.: 0199999999
(2) Expiry date: 31.12.2999
(3) Pat.no.: _____
(4) Investigator: _____
(5) Administration date: _____

PTDS LABELING
CLARA, 2023-01-15
C:\MSD\CLARA\1.0
MV45225_BX_20_MG
MV45225_1.0\1.0

(240)8989898989

Please read the info below carefully before your approval or rejection!

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For minor changes not requiring re-approval and other additional information please use the comment field directly in CLARA SAP within the Approval transaction.

Please do NOT send any handwritten comments and/or corrections at all.

General Info:	Final Booklet Index Page
	Molecule: 2 film-coated tablets baloxavir marboxil 20 mg
Master Label Document:	RPT-0327160 V1
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg
	Final Label Size: 40x100 mm / Text Area: 34x70 mm
	☐ First supply ☒ Update, Reason: countries added (old BKL MAT ID 39029776)
Material ID:	39030456
Created by:	Global Clinical Artwork Management E-mail: global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

Following section is relevant for approval

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DUTCH (BE, NL)	5
ESTONIAN (EE)	6
FRENCH (BE, FR)	7
GERMAN (BE)	8
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: ENGLISH
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

Following section is relevant for approval

	Blister with 2 film-coated tablets baloxavir marboxil 20 mg For oral use. Take as directed by your doctor. (1) Batch no. (2) Expiry date (3) Pat.no. (4) Investigator (5) Dispensing date Store at 15°C - 30°C. If completing the course at home, take ____ baloxavir marboxil tablets (from ____ box(es)), as a single dose on _____. Keep blister in outer carton. Keep out of reach of children. Return empty packaging and unused products. For clinical trial use only. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451 Manufacturer: Shionogi Pharma CO., LTD., Settsu, Osaka 566-0022, Japan	
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☐ To be corrected ☐ Approved	Print Name
Date	Signature

General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: DUTCH
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

Following section is relevant for approval

	Blister met 2 filmomhulde tabletten baloxavir marboxil 20 mg Voor oraal gebruik. Neem zoals voorgeschreven door uw arts. (1) Chargenr. (2) Vervaldatum (3) Pat.nr. (4) Onderzoeker (5) Uitgiftedatum Bewaren bij 15°C - 30°C. Als u de kuur thuis afmaakt, neemt u ____ baloxavir marboxil tabletten (uit ____ verpakking(en)), als één dosis op _____. Bewaar de strip in de buitenverpakking. Buiten het bereik van kinderen houden. Breng lege verpakkingen en niet gebruikte medicijnen terug. Uitsluitend voor gebruik in klinische studie. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451	
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☐ Approved

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 Date

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	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: ESTONIAN
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

Following section is relevant for approval

	Baloksaviirmarboxiil 20 mg, 2 õhukese polümeerikattega tabletti blistris Suukaudseks kasutamiseks. Võtke vastavalt arsti juhistele. (1) Partii number (2) Kõlblikkusaeg (3) Pt. nr. (4) Uurija (5) Väljaandmise kuupäev Hoida temperatuuril 15°C...30°C. Kui teete ravikuuri läbi kodus, võtke _____ ühekordse annusena _____ baloksaviirmarboxiil tabletti(i) (_____ karbist). Hoida blister välispakendis. Hoida lastele kättesaamatus kohas. Tagastada tühi pakend ja kasutamata tooted. Ainult kliinilises uuringus kasutamiseks. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451	
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 Date

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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: FRENCH
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

Following section is relevant for approval

	Plaquette de 2 comprimés pelliculés baloxavir marboxil 20 mg Voie orale. Prendre comme indiqué par votre médecin. (1) Lot no. (2) Date de péremption (3) Pat.no. (4) Investigateur (5) Date de dispensation Conserver à une température entre 15°C et 30°C. Si vous prenez le traitement à domicile, prenez ____ comprimés de baloxavir marboxil (à partir de ____ boîte(s)), en une seule prise le ____. Conserver la plaquette dans l'emballage extérieur. Tenir hors de la portée des enfants. Retourner les conditionnements vides et les produits non utilisés. Pour recherche biomédicale uniquement. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451	
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Date

Signature

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	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: GERMAN
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

Following section is relevant for approval

	Blister mit 2 Filmtabletten Baloxavir marboxil 20 mg Zum Einnehmen. Gemäß den Angaben Ihres Arztes einnehmen. (1) Ch.-B. (2) Verwendbar bis (3) Pat.-Nr. (4) Prüfart (5) Abgabedatum Bei 15°C - 30°C lagern. Wenn Sie die Behandlung zu Hause weiterführen, nehmen Sie Tabletten Baloxavir marboxil (aus ____ Schachtel(n)), als Einzeldosis am ____ Blisterpackung im Umkarton aufbewahren. Arzneimittel für Kinder unzugänglich aufbewahren. Leere Packungen und nicht verwendete Arzneimittel zurückgeben. Zur klinischen Prüfung bestimmt. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451	
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: INDONESIAN (ID)
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

Following section is relevant for approval

	Blister dengan 2 tablet salut selaput baloxavir marboxil 20 mg Untuk penggunaan oral. Minum seperti yang diinstruksikan oleh dokter Anda. (1) No batch (2) Tanggal daluarsa (3) No pasien (4) Peneliti (5) Tanggal pemberian Simpan diantara 15°C-30°C. Jika menyelesaikan pengobatan di rumah, minumlah ____ tablet baloxavir marboxil (dari ____ kotak), sebagai dosis tunggal pada. Simpan blister dalam karton. Hindari dari jangkauan anak-anak. Kembalikan kemasan kosong dan produk yang tidak terpakai. Hanya untuk uji klinik. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451	
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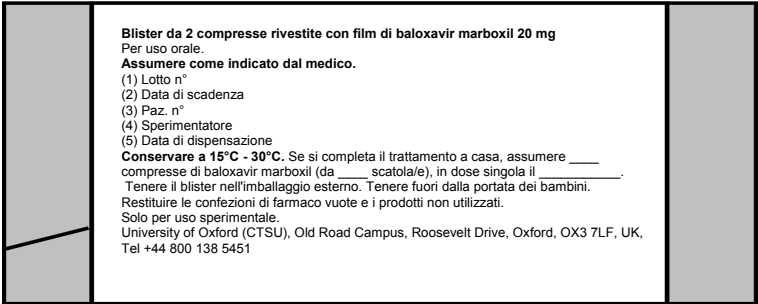
Print Name

Date

Signature

General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: ITALIAN
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
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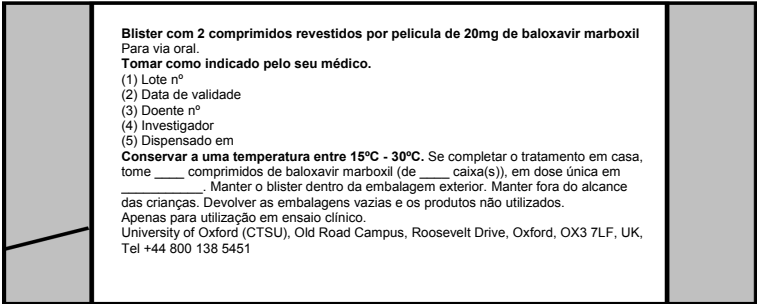
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Date

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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: PORTUGUESE (PT)
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
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Country Info:	Country Specific Booklet Page for: ROMANIAN
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Creation Date:	July 29, 2024

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	Blister cu 2 comprimate filmate baloxavir marboxil 20 mg Pentru administrare orală. A se administra conform recomandării medicului dvs. (1) Lot Nr. (2) Data expirării (3) Pac.nr. (4) Investigator (5) Data distribuirii A se pastra la temperaturi între 15°C - 30°C. Dacă finalizați tratamentul acasă, luați ____ comprimate de baloxavir marboxil (din ____ cutie(cutii)), ca doză unică la _____. A se pastra blisterele in cutie. A nu se lăsa la îndemâna copiilor. Returnați ambalajele goale și medicamentele nefolosite. Numai pentru folosire în studiu clinic. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451	
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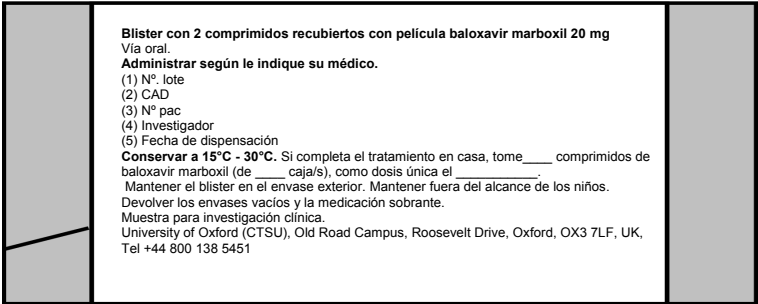
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	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: SPANISH (ES)
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
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Date

Signature

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	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: SWEDISH
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

Following section is relevant for approval

	Blister med 2 filmdragerade tabletter baloxavir marboxil 20 mg Oral användning. Tas enligt läkarens ordination. (1) Sats (2) Utg.dat (3) Pat.nr. (4) Prövare (5) Utlämningsdatum Förvaras vid 15°C - 30°C. Om du fullföljer behandlingen i hemmet, ta _____ baloxavirmarboxil-tabletter (från _____ kartong(er)) som en engångsdos den _____. Förvara blister i ytterkartongen. Förvaras utom syn- och räckhåll för barn. Återlämna tomma förpackningar och oanvända produkter. Endast för klinisk läkemedelsprövning. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451	
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Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: VIETNAMESE
Label Info:	Box: Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 40x100 mm, 34x70 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
Creation Date:	July 29, 2024

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	Ví chứa 2 viên nén bao phim baloxavir marboxil 20 mg Dùng đường uống. Sử dụng theo hướng dẫn của bác sỹ của bạn. (1) Lô sản xuất (2) Ngày hết hạn (3) Bệnh nhân số (4) Nghiên cứu viên (5) Ngày phát thuốc Bảo quản ở 15°C - 30°C. Nếu hoàn thành liệu trình tại nhà, uống ____ viên nén baloxavir marboxil (từ ____ hộp), một lần duy nhất vào _____. Giữ vỉ thuốc trong hộp. Để xa tầm tay trẻ em. Trả lại vỏ thuốc và sản phẩm không sử dụng. Sản phẩm dùng cho thử nghiệm lâm sàng. Cấm dùng cho mục đích khác. University of Oxford (CTSU), Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF, UK, Tel +44 800 138 5451	
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