

*** LABEL APPROVAL ***

Study: MV45225

Booklet Front Page

Report language: English

Template Name: 45225_BALO_20_BL_X_S

Gen.Var.Des.: 45225 30x80 BALO 20MG 2T BL SP wL

Gen.Variant: 45225_F110

Master Label Document:

Created by PTDS Global Clinical Label Coordination

Generation date: JUL/30/2024

Following section is relevant for approval:

MV45225 / RECOVERY Trial
2 film-coated tablets baloxavir
marboxil 20 mg

- (1) Batch no.: 0199999999
- (2) Expiry date: 31.12.2999
- (3) For expiry date updates see outer container.
- (4) Pat.no.: _____
- (5) Dispensing date: _____

0199999999
31.12.2999
0199999999

(240)8989898989

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

If corrections are required please kindly add your comments and/or corrections on this PDF label file (using "Review & Comment" tool of Adobe Acrobat) or on a separate Word document and attach directly in CLARA SAP with your system approval or rejection.

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: Blister: 2 film-coated tablets baloxavir marboxil 20 mg
Final Label Size: 30x80 mm / Text Area: 24x43 mm
 First supply Update, Reason: countries added (old BKL MAT ID 39029777)

Material ID: 39030457

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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ITALIAN (IT)	10

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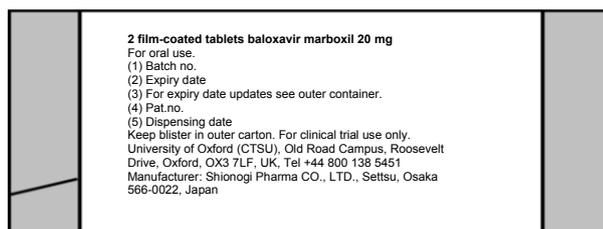
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: ENGLISH
Label Info:	Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 30x80 mm, 24x43 mm
Created by:	Clinical Label Management, F. Hoffmann-La Roche Ltd. global_clinical_artwork_mgmt.gips-gcam@roche.com
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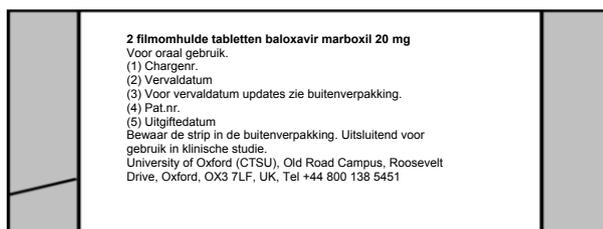
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: DUTCH
Label Info:	Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 30x80 mm, 24x43 mm
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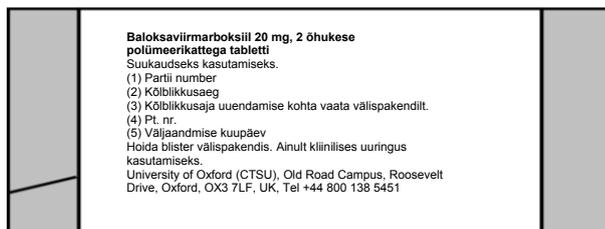
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: ESTONIAN
Label Info:	Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 30x80 mm, 24x43 mm
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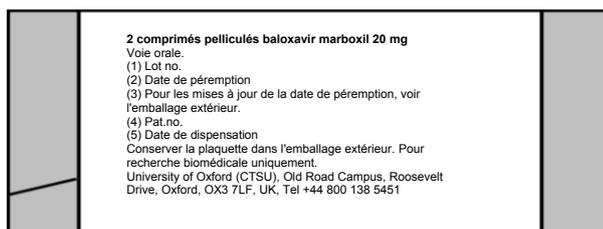
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: FRENCH
Label Info:	Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 30x80 mm, 24x43 mm
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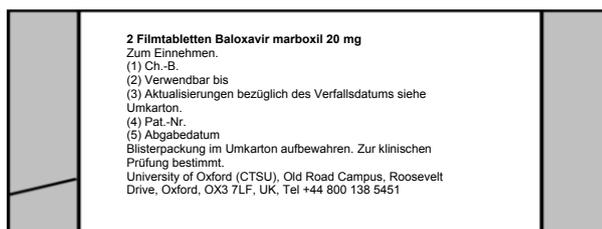
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	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: GERMAN
Label Info:	Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 30x80 mm, 24x43 mm
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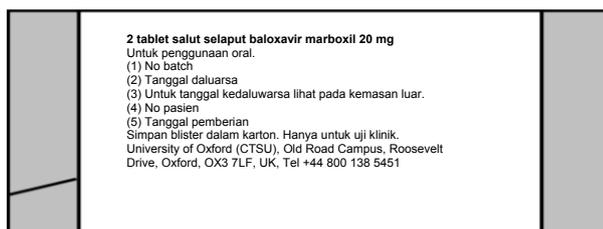
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: INDONESIAN (ID)
Label Info:	Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 30x80 mm, 24x43 mm
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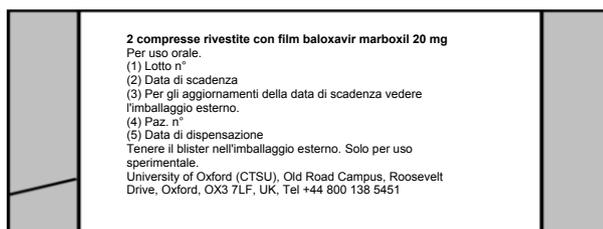
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Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: ITALIAN
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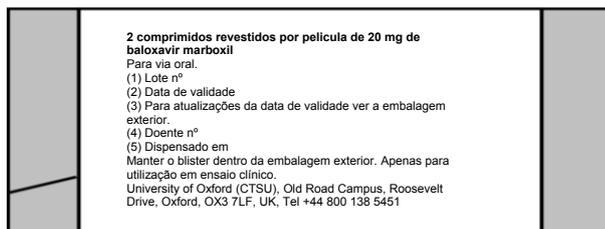
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General Info:	Final Country Booklet Label Approval
	Molecule name: 2 film-coated tablets baloxavir marboxil 20 mg
Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: PORTUGUESE (PT)
Label Info:	Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 30x80 mm, 24x43 mm
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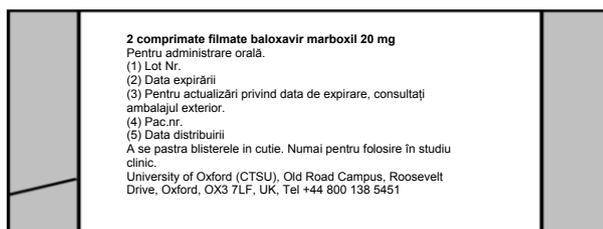
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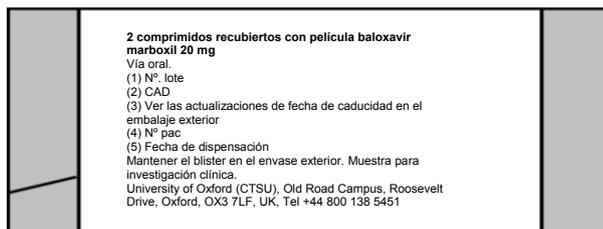
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Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: SPANISH (ES)
Label Info:	Blister with 2 film-coated tablets baloxavir marboxil 20 mg Final Label Size: 30x80 mm, 24x43 mm
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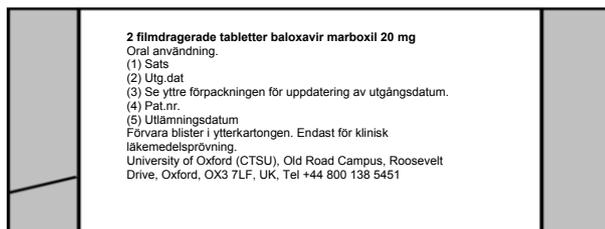
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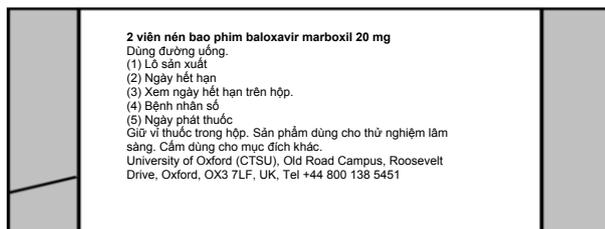
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Masterlabel Document:	RPT-0327160 V1
Country Info:	Country Specific Booklet Page for: VIETNAMESE
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