

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:	May 13, 2024

Following section is relevant for approval

	<p>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</p>	
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For External Approval Process	
Please read the info below carefully !	
If corrections are required please kindly add your comments and/or corrections on this PDF file (using the "Review & Comment" tool of Adobe Acrobat) or on a separate Word document and attach to your mail.	
To approve the labels, please print them out, sign each page, scan all and send them back as attachment to your Roche contact person by e mail.	
<input type="checkbox"/> To be corrected <input type="checkbox"/> Approved	<div style="border-bottom: 1px solid black; width: 100%;"></div> Print Name
<div style="border-bottom: 1px solid black; width: 100%;"></div> Date	<div style="border-bottom: 1px solid black; width: 100%;"></div> Signature