

***** LABEL APPROVAL *****

Study: MV45225

Booklet Front Page

Report language: English

Template Name: 45225_BALO_20_BL_BFP

Gen.Var.Des.: BFP6 30x80 BALO 2FC 20MG BL wL MV45225

Gen.Variant: 45225_BFP2

Master Label Document:

Created by PTDS Global Clinical Label Coordination

Generation date: NOV/07/2023

Following section is relevant for approval:

MV45225 / RECOVERY
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) Administration date: _____

QTO_LBL5810
QWHS_SERIALS
C=CMX.DMF+1.D
MS=4.R=0.A=0.M
=300.C7=1.3=0

(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.