

*** 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 LABEL 2023-12-31
C:\PTDS\Labels\2023-12-31
MV45225_BFP1_10
MV45225_BFP1_10
MV45225_BFP1_10

(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.