

*** LABEL APPROVAL ***

Study: MV43976

Booklet Front Page

Report language: English

Template Name: 43976_BALO_2G_BX_BFP

Gen.Var.Des.: BFP6 45x75 BALO 2G 40MG20ML BXwL MV43976

Gen.Variant: 43976_BFP5

Master Label Document:

Created by PTDS Global Clinical Label Coordination

Generation date: OCT/03/2024

Following section is relevant for approval:

MV43976 / REMAP-CAP
1 bottle of 2 g granules
baloxavir marboxil
(40 mg/20 ml)
(1) Batch no.: 0199999999
(2) Expiry date: 31.12.2999
(3) Pat.no.: _____
(4) Investigator: _____
(5) Administration date: _____
(6) Reconstitution date / time: _____

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(240)8888888888888888

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.