

Bar prints 100mm @ 100%

Shire ARTWORK

Component Code: 140662
 Description: Lialda (mesalamine) Tablets 1200/1200/1200 Shire
 Printer Code: N/A
 Shire Job No.: 388874432
 Change Control Number: 13-0018
 Revision No.: 1
 Revision: 10001 x 1745 x 1363 Shire
 Artwork Date: 15-08-13

(b) (4)

1st All Person Approval:
 Submission Mock-up: Print at Risk
 Show Final Proof: Printer's Proof

2nd All Person Approval:
 Submission Mock-up: Print at Risk
 Show Final Proof: Printer's Proof

Regulatory Responsible Person Approval:
 Signature:

Marketing Responsible Person Approval 1:
 Signature:

(b) (4)

Fonts used:
 Futura200 Book
 Helvetica750 Bold
 Helvetica750 Roman
 HelveticaNeue2105-Cn
 Strikethrough point (striked over):
 5.0 pt
 Average Text Size (body text):
 8.0 pt

PATIENT INSTRUCTIONS

ONCE-DAILY

Lialda[®]
 (mesalamine)
 delayed release
 tablets
 1.2g per tablet

Rx Only

Patient Sample—Not for Sale

Shire
 Rev. 01/07

1 blister card containing 8 tablets

Shire
 NDC 54092-476-08

www.shire.com
 Manufactured for Shire US Inc.
 774 Commonwealth Blvd.
 Wayne, PA 19087 USA
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 Di. license of Galderma S.p.A., Milan, Italy
 Made in Italy
 100002

Active Ingredient: Each tablet contains 12g of mesalamine.
 Inactive Ingredients: Camouba wax, magnesium stearate, methacrylic acid copolymer types A and B, polyethylene glycol 6000, red ferric oxide, silica (colloidal hydrate), sodium carboxymethylcellulose, sodium starch glycolate (type A), stearic acid, talc, titanium dioxide, and triethylcitrate.
 SEE PACKAGE INSERT FOR DOSAGE INFORMATION.
 KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.
 Store at room temperature 15°C to 25°C (59°F to 77°F); excursions permitted to 30°C (86°F).
 See USP Controlled Room Temperature.

3 54092 47608 4

Bar prints 100mm @ 100%

Shire ARTWORK	
Component Code:	1613/2
Description:	104841 (Lid-Label) (3) (Dr 15883) (1524) (Key
Phase Code:	PH3
Shank Job No.:	38885A25
Change Control Number:	13-0018
Version No.:	1
Dimensions:	127 x 50.8002mm
Artwork Date:	15-08-13

(b) (4)

1st APV Person Approval:	
Submission Mock-up	Print at Risk
Shire Final Proof	Printer's Proof

2nd APV Person Approval:	
Submission Mock-up	Print at Risk
Shire Final Proof	Printer's Proof

Regulatory Responsible Person Approval:	
Signature:	

Marketing Responsible Person Approval:	
Signature:	

(b) (4)

Fonts used:
FuturaStd-Book
HelveticaNeueCT16d-Bd
HelveticaNeueCT16d-Roman
MyriadPro-Book
Smallest point sized used:
4.68 pt
Average Text Size (Body Text):
5.22 pt



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOYCE A KORVICK
08/28/2013