

APPENDIX A. IMAGES OF LABELS AND LABELING RECEIVED ON FEBRUARY 23, 2021

Container labels

The Sponsor noted the following for all container labels:

The variable data (Lot and expiration date) are printed online during packaging production. The expiry dating utilizes alphabetical characters for the month and a numeric characters for the year (e.g. JAN2019).

**NDC 0597-0355-09**      **60 capsules**

**DISPENSE IN THIS UNIT OF USE CONTAINER WITH ENCLOSED MEDICATION GUIDE**

**Pradaxa<sup>®</sup>**  
(dabigatran etexilate)  
**Capsules**

**75 mg\***

Swallow capsule whole. Once opened, the product must be used within 4 months.

Pradaxa capsules are NOT substitutable on a mg-to-mg basis with other dabigatran etexilate dosage forms.

**R<sub>x</sub> only**

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Ridgefield, CT 06877 USA

Made in Italy

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L7683D

\*Each capsule contains 75 mg dabigatran etexilate equivalent to 86.48 mg dabigatran etexilate mesylate.

**Usual Dosage:** See package insert for dosage information.

Store at 20°C to 25°C (68°F to 77°F) (see insert). Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Boehringer Ingelheim

Lot      Exp.

(01) 00305970355090  
312879-03

If perforation is torn then bottle has been opened.

Store in the original package in order to protect from moisture.

NDC 0597-0108-54 60 capsules

DISPENSE IN THIS UNIT OF USE CONTAINER WITH ENCLOSED MEDICATION GUIDE

# Pradaxa<sup>®</sup> (dabigatran etexilate) Capsules

110 mg\*



Swallow capsule whole. Once opened, the product must be used within 4 months.

Pradaxa capsules are NOT substitutable on a mg-to-mg basis with other dabigatran etexilate dosage forms.

\*Each capsule contains 110 mg dabigatran etexilate equivalent to 126.83 mg dabigatran etexilate mesylate.

**Usual Dosage:** See package insert for dosage information.

Store at 20°C to 25°C (68°F to 77°F) (see insert). Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

R<sub>x</sub> only

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L8057C



(01)00305970108542

314651-02

Lot

Exp.



If perforation is torn then bottle has been opened.

Store in the original package in order to protect from moisture.

NDC 0597-0360-55 60 capsules

DISPENSE IN THIS UNIT OF USE CONTAINER WITH ENCLOSED MEDICATION GUIDE

# Pradaxa<sup>®</sup> (dabigatran etexilate) Capsules

150 mg\*



Swallow capsule whole. Once opened, the product must be used within 4 months.

Pradaxa capsules are NOT substitutable on a mg-to-mg basis with other dabigatran etexilate dosage forms.

\*Each capsule contains 150 mg dabigatran etexilate equivalent to 172.95 mg dabigatran etexilate mesylate.

**Usual Dosage:** See package insert for dosage information.

Store at 20°C to 25°C (68°F to 77°F) (see insert). Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

R<sub>x</sub> only

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L7685D



(01)00305970360551

312878-03

Lot

Exp.



Carton labeling: 60-Count Bottles







Unvarnished Area reserved for variable data to support product identifier requirements, including 2D Matrix code. This variable data (expiration date and associated prefix) are printed online during packaging production utilizing alphabetical characters for the month and a numeric characters for the year (e.g. JAN2019).

Human Readable prefixes:  
 GTN  
 SN  
 EXP  
 LOT

For more information, go to [www.PRADAXA.com](http://www.PRADAXA.com) or call 1-800-542-6257, or scan here to go to [www.PRADAXA.com](http://www.PRADAXA.com).



NDC 0597-0360-55

DISPENSE IN THIS UNIT OF USE CONTAINER WITH ENCLOSED MEDICATION GUIDE

**Pradaxa<sup>®</sup>**  
 (dabigatran etexilate)  
 Capsules

**150 mg\***

Swallow capsule whole.

Once opened, the product must be used within 4 months.

Pradaxa capsules are NOT substitutable on a mg-to-mg basis with other dabigatran etexilate dosage forms.

60 capsules

Rx only

**Pradaxa<sup>®</sup>**  
 (dabigatran etexilate)  
 Capsules

**150 mg\***

60 capsules

\*Each capsule contains 150 mg dabigatran etexilate equivalent to 172.95 mg dabigatran etexilate mesylate.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Usual Dosage: See package insert for dosage information.



0597-0360-55

NDC 0597-0360-55

DISPENSE IN THIS UNIT OF USE CONTAINER WITH ENCLOSED MEDICATION GUIDE

**Pradaxa<sup>®</sup>**  
 (dabigatran etexilate)  
 Capsules

**150 mg\***

Swallow capsule whole.

Once opened, the product must be used within 4 months.

Pradaxa capsules are NOT substitutable on a mg-to-mg basis with other dabigatran etexilate dosage forms.

60 capsules

Rx only

**Pradaxa<sup>®</sup>**  
 (dabigatran etexilate)  
 Capsules

**150 mg\***

60 capsules

Keep out of reach of children.

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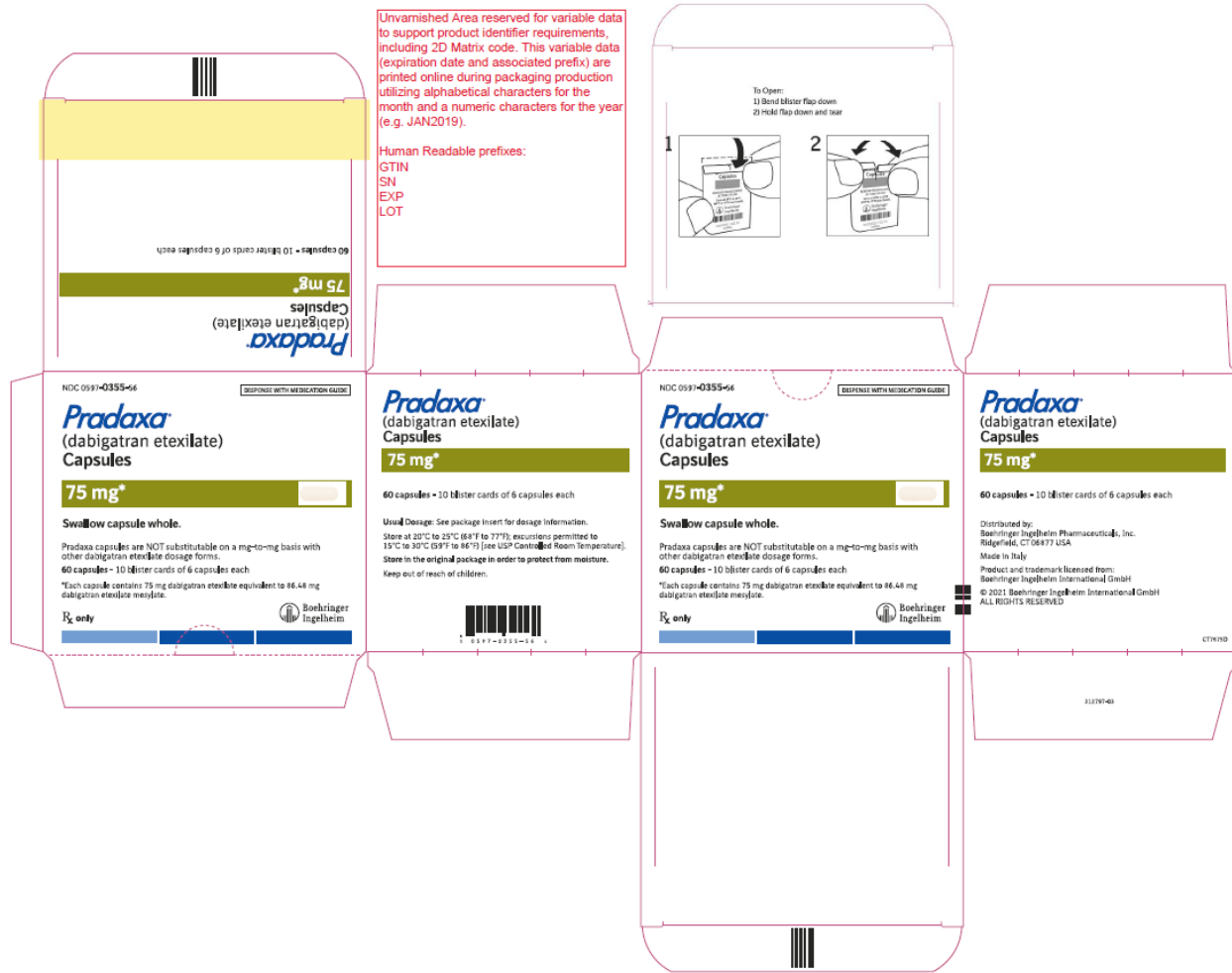
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 International GmbH  
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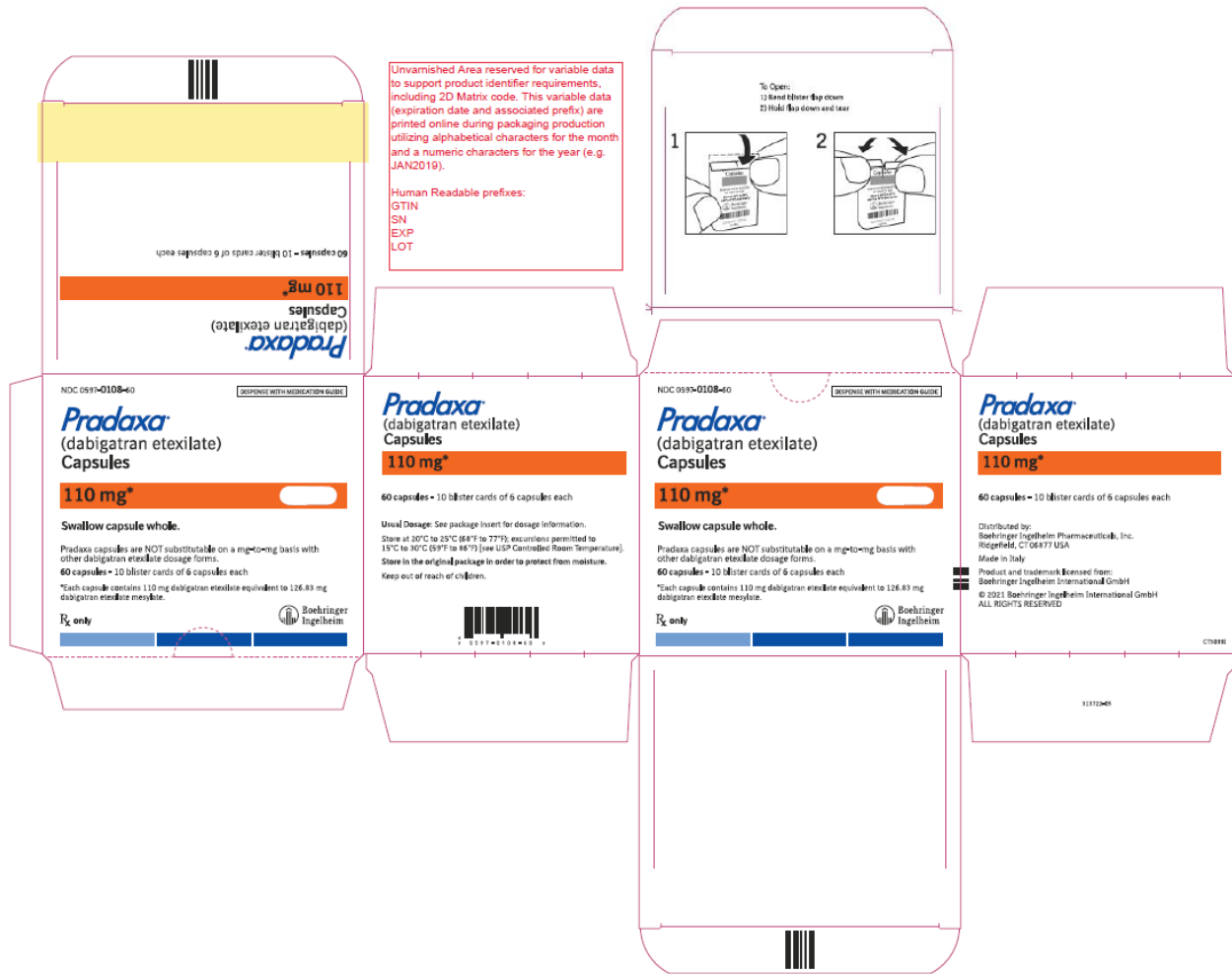


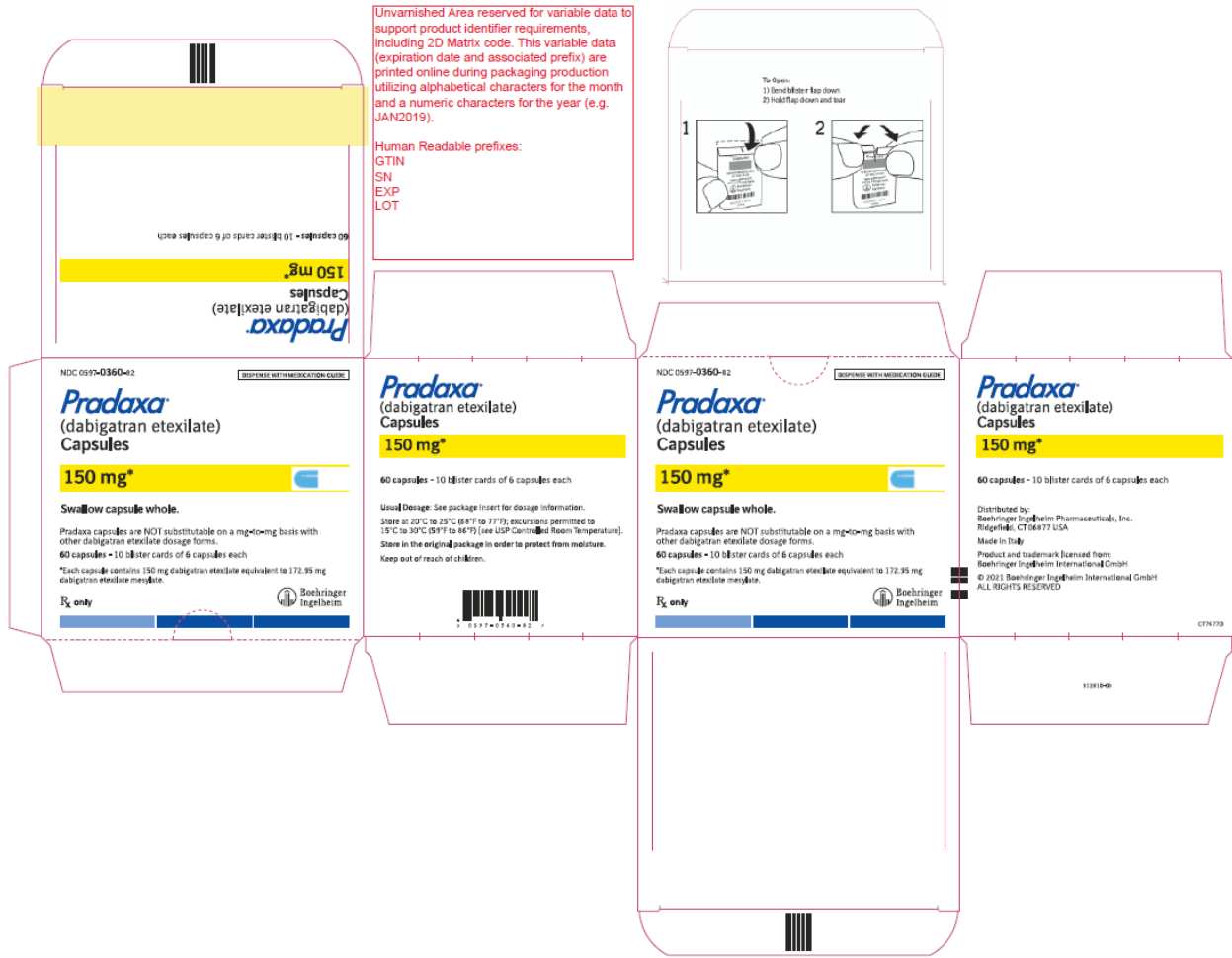
312876-03

CT76860

# Carton labeling: 60-Count Blister Packs







# Carton labeling: 12-Count Sample Blister Packs

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/s/  
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STEPHANIE L DEGRAW  
03/03/2021 05:20:04 PM

HINA S MEHTA  
03/04/2021 02:47:11 PM