

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 212184

LABELING

SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 45 mm



(b) (4)

**Theophylline
Extended-Release
Tablets**

300 mg

glenmark

Rx only **100 Tablets**

**UNARMISHED AREA FOR
EXPIRY DATE AND LOT No.
32 mm x 39 mm**

LOT: **EXP:**

105 mm **45 mm**

**Each uncoated extended-release tablet contains:
Theophylline (anhydrous), USP 300 mg.**

Usual Dosage: See package insert.

**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).**

**Keep in original container, with child-resistant
closure (as defined in the USP).**

**Manufactured by: Glenmark Pharmaceuticals Limited
Pvt. No. S-7, Conco Industrial Estate
Covale - Barder, Goa 403 513
India**

GO/DRUGS/648

**Manufactured by: Glenmark
Pharmaceuticals Inc., USA
Mahwah, NJ 07430**

08/19

**Questions? 1 (888) 721-7115
www.glenmark-mn-us.com**

(b) (4)

NDC 68462-721-05

Theophylline Extended-Release Tablets

300 mg

G
glenmark

Rx only 500 Tablets

Each uncoated extended-release tablet contains Theophylline (Anhydrous) USP 300 mg

Usual Dosage: See package insert

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].

Dispense in a well-closed container with child resistant closure [as defined in the USP]

Manufactured by Glenmark Pharmaceuticals Limited
Plot No S-7 Colvale Industrial Estate
Colvale - Bardez Goa 403 513
India

GO/DRUGS/648
Manufactured for Glenmark
Pharmaceuticals Inc., USA
Mahwah NJ 07430
09/19

3 168462172105 6
Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

UNPURNISHED AREA FOR
EXPIRY DATE AND LOT No.
32 mm x 62 mm

LOT EXP

130 mm 70 mm

(b) (4)

SAME SIZE ARTWORK
LABEL SIZE : 196 mm x 74 mm

(b) (4)

NDC 68462-721-10

Theophylline
Extended-Release
Tablets

300 mg



Rx only

1000 Tablets

Each uncoated extended-release tablet contains:
Theophylline (Anhydrous), USP, 300 mg.

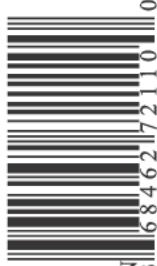
Usual Dosage: See package insert.

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].

Dispense in a well-closed container, with child-resistant closure [as defined in the USP].

Manufactured by:
Glenmark Pharmaceuticals Limited
Plot No S-7, Covalent Industrial Estate
Covalent - Bardez, Goa 403 513
India
GO/DRUGS/648

Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19



N 3 6846217211010

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

LOT:

EXP:

UNVARNISHED AREA FOR
EXPIRY DATE AND LOT No.
32 mm x 63 mm

196 mm

74 mm

SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 45 mm

UNVARNISHED AREA FOR
EXPIRY DATE AND LOT No.
32 mm x 39 mm

The diagram illustrates the packaging for Theophylline Extended-Release Tablets. The box is labeled with the following information:

- NDC 68462-722-30**
- Theophylline Extended-Release Tablets**
- 450 mg** (indicated in a purple box)
- Rx only**
- 30 Tablets**
- glenmark** logo
- Each uncoated extended-release tablet contains: Theophylline (Anhydrous), USP 450 mg.**
- Usual Dosage:** See package insert.
- 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].**
- Dispense in a well-closed container with child resistant closure [as defined in the USP].**
- Manufactured by: Glenmark Pharmaceuticals Limited Plot No S-7, Covale Industrial Estate Covale - Barter, Goa 403 513 India**
- GO/DRUGS-848**
- Manufactured for: Glenmark Pharmaceuticals Inc., USA One World Way, NJ 07450 09/19**
- A barcode is present with the number **3 68462 72230 5**.
- Text below the barcode: **Question? 1 (888) 721-7115 www.glenmarkpharmaceuticals.com**
- An arrow points from the top right corner of the box to the text: **UNVARNISHED AREA FOR EXPIRY DATE AND LOT NO. 32 mm x 39 mm**.
- Dimensions are indicated: **105 mm** (width) and **105 mm** (height).
- Labels **LOT:** and **EXP:** are shown near the bottom right corner.

(b)
(4)

(b) (4)

SAME SIZE ARTWORK
LABEL SIZE : 118 mm x 60 mm

(b) (4)

SAME SIZE ARTWORK
LABEL SIZE : 196 mm x 74 mm

(b) (4)

NDC 68462-722-05

**Theophylline
Extended-Release
Tablets**

450 mg



Rx only **500 Tablets**

Each uncoated extended-release tablet contains:
Theophylline (Anhydrous), USP, 450 mg.

Usual Dosage: See package insert.

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].

Dispense in a well-closed container, with child-resistant closure [as defined in the USP].

Manufactured by:
Glenmark Pharmaceuticals Limited
Plot No S-7, Covalent Industrial Estate
Covalent - Bardez, Goa 403 513
India

GO/DRUGS/648

Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19


N 3 6846217220513

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

LOT: EXP:

UNVARNISHED AREA FOR
EXPIRY DATE AND LOT No.
32 mm x 63 mm

74 mm

196 mm