

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 090473

LABELING



response. A single daily dose is preferably given in mid-morning or mid-afternoon, according to the patient's eating habits. In an occasional patient it may be desirable to avoid late afternoon administration. Use of benzphetamine hydrochloride is not recommended in individuals under 12 years of age.

HOW SUPPLIED

Benzphetamine hydrochloride tablets are supplied as follows:

25 mg: Pink, round tablet, debossed "EX" on one side and "25" on the other side in bottles of 14 tablets, NDC 46672-843-64, and 100 tablets, NDC 46672-843-10.

50 mg: Pink, round tablet, debossed "BENZ" on one side and "5" score "0" on the other side in bottles of 100 tablets, NDC 46672-844-10, and 500 tablets, NDC 46672-844-50.

Store at controlled room temperature 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Manufactured by:
Mikart, Inc.
Atlanta, GA 30318

Code 1025Z00

Rev. 07/10



Each tablet contains 25 mg Benzphetamine Hydrochloride. NDC 46672-843-64 

Usual adult dosage 1 tablet one to three times daily. See package insert for complete product information. Keep this and all medications out of the reach of children. Dispense in a tight container. Keep container tightly closed. Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]

Benzphetamine Hydrochloride Tablets
25 mg

Rx only
14 Tablets

Manufactured by: **MIKART, INC.**, Atlanta, GA 30318



Lot:
Exp.:

Code 1051264 Rev. 09/09

PROOF #: _____

CHECKED BY: _____

APPROVED BY: _____

SIZE: 3.75" x 1.25"



PMS (b) (4)



BLACK



Each tablet contains 25 mg Benzphetamine Hydrochloride. NDC 46672-843-10 

Usual adult dosage 1 tablet one to three times daily. See package insert for complete product information. Keep this and all medications out of the reach of children. Dispense in a tight container. Keep container tightly closed. Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]

Benzphetamine Hydrochloride Tablets
25 mg

Rx only
 100 Tablets

Manufactured by:
MIKART, INC.,
 Atlanta, GA 30318



Lot:
 Exp.:
 Code 1051Z10 Rev. 09/09

PROOF #: _____

CHECKED BY: _____

APPROVED BY: _____

SIZE: 3.75" x 1.25"



PMS (b) (4)



BLACK



Each tablet contains 50 mg Benzphetamine Hydrochloride.

Usual adult dosage: 1 tablet one to three times daily. See package insert for complete product information.

Keep this and all medications out of the reach of children.

Dispense in a tight container. Keep container tightly closed.

Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]

NDC 46672-844-10



Benzphetamine Hydrochloride Tablets

50 mg

Rx only

100 Tablets

Manufactured by:
MIKART, INC.,
Atlanta, GA 30318



Lot:
Exp.:

Code 1025Z10 Rev. 09/09

PROOF #: _____

CHECKED BY: _____

APPROVED BY: _____

SIZE: 4" x 1.625"



Each tablet contains 50 mg
Benzphetamine Hydrochloride.

Usual adult dosage: 1 tablet one to
three times daily. See package insert
for complete product information.

Keep this and all medications out of
the reach of children.

Dispense in a tight container. Keep
container tightly closed.

Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room
Temperature]

NDC 46672-844-50



**Benzphetamine
Hydrochloride Tablets**

50 mg

Manufactured by:
MIKART, INC.,
Atlanta, GA 30318



Rx only

Lot:
Exp.:

500 Tablets

Code 1025Z50

Rev. 09/09

PROOF #: _____

CHECKED BY: _____

APPROVED BY: _____

SIZE: 6.625" x 2.625"

