

BIDEX-400 - guaifenesin tablet
SJ Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BIDEX-400

Drug Facts

Active ingredient

(in each immediate release tablet)

Guaifenesin 400 mg

Purpose

Expectorant

Uses

Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a cough that occurs with too much phlegm (mucus)

Stop use and ask doctor if cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and over:	1 tablet every 4 hours, not to exceed 6 tablets in 24 hours.
Children under 12 years of age:	consult a doctor.

•Take with a full glass of water

Other information

- Tamper-evident by foil seal under cap. Do not use if foil seal is broken or missing
- Store between 20°-25°C (68°-77°F).

- Supplied in a tight, light-resistant container with a child-resistant cap.
- Bidex-400 Tablets are white to off white, biconex, capsule shaped tablets, debossed "649" bisect "649" on one side and plain on the other side.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, maltodextrin, povidone, silicified microcrystalline cellulose, and stearic acid. May also contain sodium starch glycolate.

Questions or comments?

1 (877) 604-7575

Distributed by:

SJ Pharmaceuticals

4200 North Parkway NW, Bldg. 12

Atlanta, GA 30327

Rev. 10/12

Product Packaging

The packaging below represents the labeling currently used.

Principal display panel for 100 tablets label:

NDC 24839-777-01

**BIDEX[®]-400
TABLETS**

Each immediate release tablet contains:

Guaifenesin.....400 mg

Expectorant

CONTENTS: 100 Tablets

SJP

SJ PHARMACEUTICALS

NDC 24839-777-01

BIDEX-400 TABLETS

Each immediate release tablet contains:
Guaifenesin 400 mg

Expectorant

CONTENTS: 100 Tablets



Drug Facts	Purpose
Active ingredient (in each immediate release tablet) Guaifenesin 400 mg..... Expectorant	
Uses Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.	
Warnings Ask a doctor before use if you have: <ul style="list-style-type: none"> a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema a cough that occurs with too much phlegm (mucus) Stop use and ask doctor if cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition. If pregnant or breast-feeding, ask a health professional before use. KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions Adults and children 12 years of age and over: 1 tablet every 4 hours, not to exceed 6 tablets in 24 hours. Children under 12 years of age: consult a doctor. Take with a full glass of water.	
Other information <ul style="list-style-type: none"> Tamper-evident foil seal under cap. Do not use if foil seal is broken or missing. Store between 20°-25°C (68°-77°F). Supplied in a tight, light-resistant container with a child-resistant cap. Bidex-400 Tablets are white to off white, biconvex, capsule shaped tablets, debossed "649" bisect "649" on one side and plain on the other side. 	
Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, hypromellose, methocel K100, povidone, silicified microcrystalline cellulose, and stearic acid. May also contain sodium starch glycolate.	
Questions or comments? 1 (877) 604-7575	

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M 3 24839 77701 9

Lot/Exp. date.

BIDEX-400

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24839-777
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	400 mg

Inactive Ingredients

Ingredient Name	Strength
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Hypromelloses (UNII: 3NXW29V3WO)	
Maltodextrin (UNII: 7CVR7L4A2D)	
Povidones (UNII: FZ989GH94E)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Stearic Acid (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white to off white)	Score	2 pieces
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	649;649
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24839-777-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/09/2012	

Labeler - SJ Pharmaceuticals (845662720)**Registrant** - Pernix Manufacturing, LLC (078641814)**Establishment**

Name	Address	ID/FEI	Business Operations
Pernix Manufacturing, LLC dba Great Southern Laboratories		078641814	manufacture(24839-777)

Revised: 11/2012

SJ Pharmaceuticals