



Standard Pharmaceutical Product Information (Rx Product Only)

PRODUCT INFORMATION

Introduction Type: New Item

Final Version

Date: 3/15/2019

Company Name: TARGI Pharma, Inc.

Application: ANDA

Application: A202765

Application: A202765

Proprietary Name (if applicable) and Established Name: Benzostatate Capsules, USP

Individual Unit NDC: 61224-010-80

UPC: 61224-010-80

Other Temperature Range Requirement (write in):

Controlled Room - between 20 and 25 C (68 - 77 F)

SKU: 61224-010-80

CVA Code: 0000

MYX Code: 0000

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

Description: Benzostatate Capsules, USP 100mg

Active Ingredient(s): Benzostatate

URL for Additional Product Information: www.targipharma.com

Address 2: Room 205

State: IL

Room: 205

Zip: 61080

City: South Beloit

State: IL

Room: 205

Zip: 61080

Key Contact: Melissa Bradley

Email: mbradley@targipharma.com

Phone Number: 815-824-7885

Far: 815-824-7887

Product Therapeutic Classification:

ADDITIONAL PRODUCT INFORMATION

Is the Product... a legend device? No

reverse numbered? No

Is the Product... co-licensed? No

Is the Product... Direct-Ship Only? No

Is the Product... Neither? No

Product Shape: Oval-shaped capsule

Product Color: yellow

Product Imprint: 2

PRODUCT DESCRIPTION INFORMATION

Size: 500 Capsules

Strength: 100mg

Dosage Form: Capsules

Product Shape: Oval-shaped capsule

Product Color: yellow

Product Imprint: 2

Country of Origin: Ghana

Is this product covered under the Trade Agreements Act (TAA)? No

FOR GENERIC DRUG PRODUCTS

Authorized Generic

*If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AA

II. Generic Equivalent to What Brand?: Tessalon

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? No

Is product exempt from DSCSA? No

GLN: 0351224000001

GLN: 0351224000001

Other exemption - Write in:

Is product repackaged? No

Is product sold by manufacturer's exclusive distributor? No

Has FDA granted value/reception/exemption for product? No

If Yes, was original product purchased direct from mfr? No

If Yes, attach documentation from FDA.

GTIN PRODUCT INFORMATION

Serialized? Yes

Item 11/1/2018

Level: X

Unit: X

Quantity: 20

GTIN-14: 00351224010804

Case: 50351224010809

Case: 50351224010809

Case: 50351224010809

Case: 50351224010809

Item: X

Unit: X

Quantity: 20

Case: 50351224010809

Case: 50351224010809

Case: 50351224010809

Case: 50351224010809

Case: 50351224010809

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature - Indicate the USP temperature range for this product. Temperature Range: Controlled Room - between 20 and 25 C (68 - 77 F)

b. Contact for temperature excursion questions: Name: Mat Hardin, 815-824-7885, mhardin@targipharma.com

c. Special regulators for product in any states? No

d. Store product (unit of sale) upright? Yes

e. Shelf life: Product product (unit of sale) from light? Yes

Initial shelf life at launch (if different): 24 Months

What is the NDC selling unit? 1 Bottle of 500 capsules

Minimum order quantity? 24

If Yes, how many of which package type? 6 Each

Other: Write in: InterCarton/Pack

ORDER INFORMATION

Rec. sell unit to customer? Each

Rec. bill unit to pharmacy: Each

Weight Lbs. 0.0004

Depth 2.5

Height 5.56

Width 2.5

Volume (Cubo) 1

Pieces: 1

Item: 0.0004

Box/Case/Bundled/Inner Pack: 2.5

Case: 30.98

Pallet: 21.25

UPC: 16.14

Case: 1.181

Case: 98

COST INFORMATION

Regular Cost: \$114.65

Invoice Cost (WAC) (\$): \$114.65

Federal Excise Tax Per Unit of Sale: \$152/2019

Final Price: \$114.65

Net Price: \$114.65

Final Price: \$114.65

WHOLESALE USER ONLY*

Vendor #:

Invoice Code #:

Federal Excise Tax Code #:

As of date:

Signature:

Signature:

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Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. See new p. 3 for Designated Drop Ship Only.



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3
MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic? No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No
- Is the product a CA Prop 65 carcinogen? No
- Is the product a CA Prop 65 reproductive toxicant? No
- Does the product label bear a CA Prop 65 warning? No

c. Contact Hazard?

d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

Is this product regulated for shipment by DOT or IATA? (If yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity? No

RQ Threshold: No

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit? (If yes, identify method below)

- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit: DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101):
- SP#

ADDITIONAL STORAGE INFORMATION

Is the Product...

- Controlled Substance? No
- Controlled by State(s)? No
- ARCOS Reportable? No
- Schedule No. (inc. N for non-narcotic)
- Controlled Substance Code
- Listed Chemical (List I or II) No
- If yes, indicate which:
- Is it a scheduled listed chemical product? No

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospital, clinic and physician offices Yes
- Restricted to retail pharmacy only: No
- Restricted to hospital, clinics, and physician offices only: No
- Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

- Organic Corrosive
- Inorganic Oxidizer
- Steroid/Androgen Contact Hazard

Aerosol Class: Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, Pledge program?)

REMS:

- No
- REMS Program Manager Name: Phone:
- Supplier Manages REMS registry exclusively:
- Wholesale distributor support:
- Provider Name:
- Site Enrollment Number assigned:
- By Supplier:
- DEA #:
- PCPDP #:
- NPI #:

Comments:

Registry:

Registry Program Contact Name:

Phone:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or email: customercare@lagpharma.com

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Standard Order Receipt and Processing

Purchase orders may be accepted by:

a. EDI	Yes		
b. Autofax	Yes	Fax Number:	815-624-7687
c. Fax	Yes	Fax Number:	815-624-7687
d. Phone only		Phone No.:	855-225-8244
e. Supplier Web Site only	No	Site Address:	

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #:

Name:	855-225-8244
Phone:	<input type="text"/>

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order: Yes

Drop Ship service fee billed with each order: No

Drop Ship miscellaneous fees billed: No

Comments:

Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #:

Physician State License #:

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Miscellaneous Notes:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier: 12:00pm Central

Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt: No

Ships for second day receipt: No

Ships regular ground for 3-10 days receipt: Yes

Overnight and Priority Overnight PO Processing

Overnight receipt available: Yes

PO Receipt cut off time: 12:00pm Central

Days of week overnight is available:

<input checked="" type="checkbox"/>	Monday
<input checked="" type="checkbox"/>	Tuesday
<input checked="" type="checkbox"/>	Wednesday
<input checked="" type="checkbox"/>	Thursday
<input checked="" type="checkbox"/>	Friday

Priority Overnight receipt available: Yes

PO Receipt Cut off time: 12:00pm

Saturday Overnight receipt available: No

PO Receipt Cut off time:

Order receipt method: Yes No

Phone #: 855-225-8244

Fax #: 815-624-7687

EDI: Yes No

Overnight Fees apply: Yes No

Other fees apply:

Return Instructions

Contact # if product is received damaged: 855-225-8244

Is product returnable for credit: Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? Yes

If so, which states? Other requirements? Comments?

Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or email

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

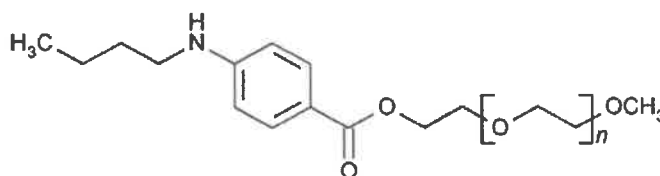
Is product order for restocking purposes?



Section 1. Identification

Identification of the product:

Product name Benzonatate Capsules,
Formula C₃₀H₅₃NO₁₁
Chemical Name 2,5,8,11,14,17,20,23,26-nonaoxaocacosan-28-yl *p*-(butylamino) benzoate



Therapeutic Category Benzonatate capsules, a non-narcotic oral antitussive agent

Manufacturer / supplier identification:

Company CSPC NBP Pharmaceutical Co.,LTD
Address No.88 Yangzi Road,Economic and Technological Development Zone, Shijiazhuang, Hebei Province, P.R.China
Contact for information Tel.: +86 311 83092888 Fax: +86 311 83092777
Emergency telephone No. Tel.: +86 311 83092888

Section 2. Hazard(s) Information

Dose and Administration Adults and Children over 10 years of age:Usual dose is one 100 mg or 200 mg capsule three times a day as needed for cough. If necessary to control cough, up to 600 mg daily in three divided doses may be given.Benzonatate Capsules should be swallowed whole. Benzonatate Capsules are not to be broken, chewed, dissolved, cut or crushed.

ADVERSE REACTIONS Potential Adverse Reactions to Benzonatate Capsules may include:



Material Safety Data Sheet

Version:1.0

CSPC BENZONATATE CAPSULES,

Strength: 200 mg & 100 mg

Hypersensitivity reactions including bronchospasm, laryngospasm, cardiovascular collapse possibly related to local anesthesia from chewing or sucking the capsule.

CNS: sedation; headache; dizziness; mental confusion; visual hallucinations.

GI: constipation; nausea; GI upset.

Dermatologic: pruritus; skin eruptions.

Other: nasal congestion; sensation of burning in the eyes; vague “chilly” sensation; numbness of the chest;

OVERDOSAGE

Intentional and unintentional overdose may result in death, particularly in children.

The drug is chemically related to tetracaine and other topical anesthetics and shares various aspects of their pharmacology and toxicology. Drugs of this type are generally well absorbed after ingestion.

Medical Conditions

Hypersensitivity:

Sever hypersensitivity reactions (including bronchospasm, laryngospasm and cardiovascular collapse) have been reported which are possibly related to local anesthesia from sucking or chewing the capsules intervention with vasopressor agents and supportive measures.

Psychiatric Effects:

Isolated instances of bizzare behavior, including mental confusion and visual hallucinations, have also been reported in patients taking benzonatate capsules in combination with other prescribed drug.

Contraindications

Severe hypersensitivity reactions (including bronchospasm, laryngospasm and cardiovascular collapse) have been reported which are possibly related to local anesthesia from sucking or



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CSPC BENZONATATE CAPSULES,

Strength: 200 mg & 100 mg

chewing the capsule instead of swallowing it. Severe reactions have required intervention with vasopressor agents and supportive measures. Isolated instances of bizarre behavior, including mental confusion and visual hallucinations, have also been reported in patients taking benzonatate capsules in combination with other prescribed drugs.

Pregnancy Comments

Pregnancy Category C. Animal reproduction studies have not been conducted with benzonatate capsules. It is also not known whether benzonatate capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzonatate capsules should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in children below the age of 10 have not been established. Accidental ingestion resulting in death has been reported in children below age 10. Keep out of reach of children.

Section 3. Composition / information on Ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Benzonatate	Not Found	104-31-4
Inactive Ingredients :		
Gelatin	Not Found	9000-70-8
Glycerin	Not Found	56-81-5
Methylparaben	Not Found	99-76-3
Propylparaben	Not Found	94-13-3

Section 4. First - aid Measures

General Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive



medical attention.

Overdose Treatment

In case of overdose, seek medical attention immediately. Evacuate gastric contents and administer copious amounts of activated charcoal slurry. Even in the conscious patient, cough and gag reflexes may be so depressed as to necessitate special attention to protection against aspiration of gastric contents and orally administered materials. Convulsions should be treated with a short-acting barbiturate given intravenously and carefully titrated for the smallest effective dosage. Intensive support of respiration and cardiovascular-renal function is an essential feature of the treatment of severe intoxication from overdosage. Do not use CNS stimulants.

Section 5. Fire - fighting Measures

Flash point	Not Found	Auto-Ignition Temperature	Not Found
Upper Flammable Limit	Not Found	Lower Flammable Limit	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	Fire and Explosion Hazard	This material is assumed to be combustible.

Fire Fighting Procedure As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.



Material Safety Data Sheet

Version:1.0

CSPC BENZONATATE CAPSULES,

Strength: 200 mg & 100 mg

Section 7. Handling and Storage

Storage Store at 20° to 25°C (68° to 77°F) excursions permitted between 15° to 30°C (59° to 86°F). PROTECT FROM LIGHT.

Incompatibilities No data available.

Section 8. Exposure Controls / Personal Protection

Respiratory Protection Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing Protective clothing is not normally necessary, however it is good practice to use apron.

Engineering Control Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Section 9. Physical and Chemical Properties

Appearance Benzonatate capsules USP, 200 mg and 100 mg are light yellow-colored, oval-shaped soft gelatin capsules, imprinted with “2” or “1” containing pale yellow-colored clear viscous liquid.

Solubility in water	No Data Available	Odour	Odourless
Boiling point	No Data Available	Melting Point	No Data Available
Evaporation rate	No Data Available	Vapour density	No Data Available



Material Safety Data Sheet

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CSPC BENZONATATE CAPSULES,

Strength: 200 mg & 100 mg

Reactivity in water	No Data Available	Evaporation rate	No Data Available
% Volatile by volume	No Data Available	Specific gravity	No Data Available
Vapour pressure	No Data Available	Other information	No Data Available

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	Stable	Stable under normal Ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	Hazardous Reaction	No data available.
Incompatibilities	No data available.		

Section 11. Toxicological Information

General	Handling of formulated product is not expected to cause any adverse affects.The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is capsules.
Other	No data available.

Section 12. Ecological Information

Do not allow product to enter drinking water supplies, waste water or soil.

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 202765.



CSPC

Material Safety Data Sheet

BENZONATATE CAPSULES,

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Section 16. Other information

None.