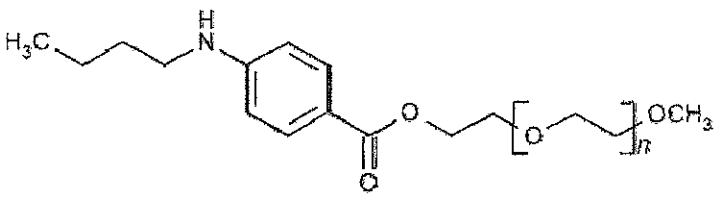
Section 1. Identification

Identification of the product:

Product name	Benzonatate Capsules, USP
Formula	$C_{30}H_{53}NO_{11}$
Chemical Name	2,5,8,11,14,17,20,23,26-nonaoxaoctacosan-28-yl *p*-(butylamino) benzoate



Therapeutic Category	Benzonatate capsules, USP, 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:

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

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.

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 are light yellow-colored, oval-shaped soft gelatin capsules, imprinted with "2" 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

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.

Section 16. Other information

None.

Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Post Launch Change | [ ] Final Version | Date: 7/14/2016

PRODUCT INFORMATION

Company Name: TAGI Pharma, Inc. | Application: ANDA
Application Number for NDA/ANDA/BLA, Med Device: A202765
Rx Product/Proprietary Name: Benzonatate Capsules USP
NDC: 51224-001-50 | UPC:
CVX Code: | MVX Code:
Description: Benzonatate Capsules, USP 200mg
Active Ingredients: Benzonatate
URL for Additional Product Information:

Address: 722 Progressive Lane | Address 2: Room 205
City: South Beloit | State: IL | Zip: 61080
Key Contact: Melissa Bradley | Email: mbradley@tagipharma.com
Phone Number: 815-624-7685 | Fax: 815-624-7014

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AA | II. Brand Name: Tessalon
III. Generic Equivalent for Brand: Benzonatate

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes | DUNS: 963322560
Is product exempt from DSCSA? No
If yes, select exemption:
Other exemption - Write in:
Is product repackaged? No | If Yes, was original product purchased direct from mfr?
Is product sold by manufacturer's exclusive distributor? Yes
Are any waivers granted for product ID/barcode? No | If yes, attach documentation from FDA

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

- [ ] I. Freezer – between -25 and -10 C (-13° – 14° F)
- [ ] II. Cold – between 2 and 8 C (36° – 46° F)
- [ ] III. Cool – between 8 and 15 C (46° – 59° F)
- [x] IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
- [ ] V. Avoid Excessive Heat – above 40 C (>104° F)
- [ ] VI. Other Temperature Range Requirement (write in)
- [ ] VII. No Requirement

b. Contact for temperature excursion questions:
Name: Mat Mathis
Number: 815-624-7685
Is this product to be shipped to customers on ice? No
Is this product to be shipped to customers on dry ice? No

c. Special regulations for product in certain states? No
Special returns requirements for this product? No

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

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

ADDITIONAL PRODUCT INFORMATION

Is the Product... Direct Ship Item
Legend Device? No
State Control? No
ARCOS reportable? No
Co-Licensed? No
Controlled Substance? No
Schedule No.? N/A
(incl. N for non-narcotic)
Controlled Substance Code: N/A
Hazardous Material/Cytotoxic Agent? No

Is Item... Neither
If Unit Dose, is item bar coded to unit dose for hospital scanning?
Is it reverse numbered?

ORDER INFORMATION

Unit of Sale:
- [x] Bottle
- [ ] Box/Carton
- [ ] Ampule
- [ ] Glass
- [ ] Tube
- [ ] Vial Liquid Sgl
- [ ] Vial Liquid Multi
- [ ] Vial Powder Sgl
- [ ] Vial Power Multi
- [ ] Other: Write In

What is the NDC selling unit? 1 bottle of 100 capsules
(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? Yes
If Yes, how many of which package type?
12 Each
Inner/Carton/Pack
Case

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width:	Volume (Cube)	# Pieces:
Item:	0.11	1.57	2.78	1.57		
Box/ Carton:						
Case:	1.32	5.03	6.69	3.34		
Pallet:						
UPC:	Case:					
	Carton:					

PHARMACY ORDER/BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:
- [ ] Each
- [ ] Gram
- [ ] Milliliter

Other Product Information

Size/Strength/Form: 200mg Capsules
Product Shape: Oval-shaped capsule
Product Color: Yellow
Product Imprint: 2

COST INFORMATION

Regular Cost Per Unit of Sale ($)	Invoice Cost (WAC) ($)	Federal Excise Tax Per Unit of Sale
	$32.19	

As of date: 7/14/2016

WHOLESALER USE ONLY

Vendor #:
Whsl. Code #:
Fineline Code:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: Melissa Bradley

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

- ☐ Carcinogen
- ☐ Reproductive Toxicant
- ☐ Both
- ☐ Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
No (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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization

		Level		How?		GTIN-14
Serialized?	No	☐ Item	☐ 2D	☐ Linear	☐ RFID	
If not, when?	11/1/2017	☐ Box/Carton	☐ 2D	☐ Linear	☐ RFID	
Items aggregated to case?		☐ Case	☐ 2D	☐ Linear	☐ RFID	
		☐ Pallet	☐ 2D	☐ Linear	☐ RFID	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

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

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

- ☐ Organic
- ☐ Antineoplastic
- ☐ Corrosive
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Oxidizer

☐ Aerosol Class; Identify NFPA Storage Level:

☐ Listed Chemical (List I or II) (Indicate or Write-in below):

- ☐ Ephedrine
- ☐ Pseudoephedrine
- ☐ Phenylpropanolamine
- ☐ Iodine (≥2.2%)
- ☐ Other:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 800-397-9228

Is product returnable for credit: Yes

URL/Link to returns policy: N/A

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: customercare@tagipharma.com

GLASS 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:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here: N/A

MISCELLANEOUS NOTES and/or Image of Product Barcode

Release DATE

Standard Pharmaceutical Product Information (Page 3)

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

Order Method for Designated Drop Ship Product

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	Yes	Phone No.:	800-397-9228
e. Supplier Web Site only	No	Site Address:	

Minimum Order Quantity:

Supplier's Customer Service Number: 800-397-9228

Contracted 3PL company / contact #: Name:

Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier

Cut off time: 12:00 PM Central

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

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:

Overnight and Priority Overnight PO Processing

Overnight receipt available: Yes

PO Receipt cut off time: 12:00 PM Central

Days of week overnight is available:

- [x] Monday
- [x] Tuesday
- [x] Wednesday
- [x] Thursday
- [ ] Friday

Priority Overnight receipt available: Yes

PO Receipt Cut off time: 12:00 PM

Saturday Overnight receipt available: Yes

PO Receipt Cut off time:

Order receipt method:

Phone:	Yes	Phone #:	800-397-9228
Fax:	Yes	Fax #:	815-624-7687
EDI:	Yes		

Overnight Fees apply: Yes

Other fees apply: No

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:

REMS or Registry Restrictions

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:

Comments

Return Instructions

Contact # if product is received damaged: 800-397-9228

Is product returnable for credit: Yes

URL/Link to returns policy: N/A

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

If so, which states? Other requirements? Comments?

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?

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: