

**BENZONATATE- benzonatate capsule, gelatin coated
DIRECT RX**

BENZONATATE 200mg

DESCRIPTION

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CLINICAL PHARMACOLOGY

-

INDICATIONS AND USAGE

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WARNINGS

-

CONTRAINDICATIONS

-

PRECAUTIONS

-

ADVERSE REACTIONS

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OVERDOSAGE

-

DOSAGE AND ADMINISTRATION

-

HOW SUPPLIED

-

PRODUCT PACKAGING

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Mfg For: TAGI Pharma, Inc.
South Berlin, IL 61080
NDC 51224-001-50

Mfg Lot:
2/16/2016

**BENZONATATE
200mg 20 Caps**

Generic For: **TESSALON PERLES**
Each soft gelatin capsule contains: Benzonatate. USP
200mg

Lot# Prod# 763-20 Discard After: 04/17

Packaged and Distributed By: **DIRECT Rx**

Alpharetta, GA 30005

M

NDC 61919-763-20

AE74F

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.

RX ONLY-KEEP OUT OF REACH OF CHILDREN

Dosage: See package insert. Store between 68-77 degrees F

BENZONATATE 200mg
NDC 61919-763-20 20 Cap
Lot Exp Date 04/17
Mfg NDC 51224-001-50

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BENZONATATE

benzonatate capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-763(NDC:51224-001)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZONATATE (UNII: 5P4DHS6ENR) (BENZONATATE - UNII:5P4DHS6ENR)	BENZONATATE	200 mg

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	N01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-763-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202765	02/15/2016	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-763)

Revised: 2/2016

DIRECT RX