

BENZTROPINE MESYLATE- benztropine mesylate tablet
NCS HealthCare of KY, Inc dba Vanguard Labs

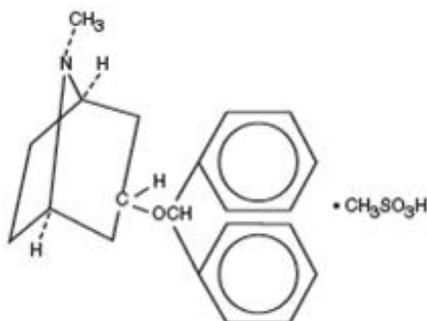
BENZTROPINE MESYLATE TABLETS USP

DESCRIPTION

Benztropine mesylate USP is a synthetic compound resulting from the combination of the active portions of atropine and diphenhydramine. It is a crystalline white powder, very soluble in water.

Chemically it is 3 α -(diphenylmethoxy) 1 α H, 5 α H-tropane methane-sulfonate.

Structural Formula:



C₂₁H₂₅NO•CH₄O₃S M.W. 403.54

These orally administered tablets are supplied in three strengths (0.5 mg, 1 mg, and 2 mg per tablet). Inactive ingredients are anhydrous lactose, microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycolate, magnesium stearate.

CLINICAL PHARMACOLOGY

Benztropine mesylate possesses both anticholinergic and antihistaminic effects, although only the former have been established as therapeutically significant in the management of parkinsonism.

In the isolated guinea pig ileum, the anticholinergic activity of this drug is about equal to that of atropine; however, when administered orally to unanesthetized cats, it is only about half as active as atropine.

In laboratory animals, its antihistaminic activity and duration of action approach those of pyrilamine maleate.

INDICATIONS AND USAGE

For use as an adjunct in the therapy of all forms of parkinsonism.

Useful also in the control of extrapyramidal disorders (except tardive dyskinesia - see PRECAUTIONS) due to neuroleptic drugs (e.g., phenothiazines).

CONTRAINDICATIONS

Hypersensitivity to any components of benztropine mesylate tablets.

Because of its atropine-like side effects, this drug is contraindicated in pediatric patients under three years of age, and should be used with caution in older pediatric patients.

WARNINGS

Safe use in pregnancy has not been established.

Benztropine mesylate may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle.

When this drug is given concomitantly with phenothiazines, haloperidol, or other drugs with anticholinergic or antidopaminergic activity, patients should be advised to report gastrointestinal complaints, fever or heat intolerance promptly. Paralytic ileus, hyperthermia and heat stroke, all of which have sometimes been fatal, have occurred in patients taking anticholinergic-type antiparkinsonism drugs, including benztropine mesylate, in combination with phenothiazines and/or tricyclic antidepressants.

Since benztropine mesylate contains structural features of atropine, it may produce anhidrosis. For this reason, it should be administered with caution during hot weather, especially when given concomitantly with other atropine-like drugs to the chronically ill, the alcoholic, those who have central nervous system disease, and those who do manual labor in a hot environment. Anhidrosis may occur more readily when some disturbance of sweating already exists. If there is evidence of anhidrosis, the possibility of hyperthermia should be considered. Dosage should be decreased at the discretion of the physician so that the ability to maintain body heat equilibrium by perspiration is not impaired. Severe anhidrosis and fatal hyperthermia have occurred.

PRECAUTIONS

General

Since benztropine mesylate has cumulative action, continued supervision is advisable. Patients with a tendency to tachycardia and patients with prostatic hypertrophy should be observed closely during treatment.

Dysuria may occur, but rarely becomes a problem. Urinary retention has been reported with benztropine mesylate.

The drug may cause complaints of weakness and inability to move particular muscle groups, especially in large doses. For example, if the neck has been rigid and suddenly relaxes, it may feel weak, causing some concern. In this event, dosage adjustment is required.

Mental confusion and excitement may occur with large doses, or in susceptible patients. Visual hallucinations have been reported occasionally. Furthermore, in the treatment of extrapyramidal disorders due to neuroleptic drugs (e.g., phenothiazines), in patients with mental disorders, occasionally there may be intensification of mental symptoms. In such cases, antiparkinsonian drugs can precipitate a toxic psychosis. Patients with mental disorders should be kept under careful observation, especially at the beginning of treatment or if dosage is increased.

Tardive dyskinesia may appear in some patients on long-term therapy with phenothiazines and related agents, or may occur after therapy with these drugs has been discontinued. Antiparkinsonism agents do not alleviate the symptoms of tardive dyskinesia, and in some instances may aggravate them. Benztropine mesylate is not recommended for use in patients with tardive dyskinesia.

The physician should be aware of the possible occurrence of glaucoma. Although the drug does not appear to have any adverse effect on simple glaucoma, it probably should not be used in angle-closure glaucoma.

Drug Interactions

Antipsychotic drugs such as phenothiazines or haloperidol; tricyclic antidepressants (see WARNINGS).

Pediatric Use

Because of the atropine-like side effects, benztropine mesylate should be used with caution in pediatric patients over three years of age (see CONTRAINDICATIONS).

ADVERSE REACTIONS

The adverse reactions below, most of which are anticholinergic in nature, have been reported and within each category are listed in order of decreasing severity.

Cardiovascular: Tachycardia.

Digestive: Paralytic ileus, constipation, vomiting, nausea, dry mouth.

If dry mouth is so severe that there is difficulty in swallowing or speaking, or loss of appetite and weight, reduce dosage, or discontinue the drug temporarily.

Slight reduction in dosage may control nausea and still give sufficient relief of symptoms. Vomiting may be controlled by temporary discontinuation, followed by resumption at a lower dosage.

Nervous System: Toxic psychosis, including confusion, disorientation, memory impairment, visual hallucinations; exacerbation of pre-existing psychotic symptoms; nervousness; depression; listlessness; numbness of fingers.

Special Senses: Blurred vision, dilated pupils.

Urogenital: Urinary retention, dysuria.

Metabolic/Immune or Skin: Occasionally, an allergic reaction, e.g., skin rash, develops. If this can not be controlled by dosage reduction, the medication should be discontinued.

Other: Heat stroke, hyperthermia, fever

OVERDOSAGE

Manifestations

May be any of those seen in atropine poisoning or antihistamine overdose: CNS depression, preceded or followed by stimulation; confusion; nervousness; listlessness; intensification of mental symptoms or toxic psychosis in patients with mental illness being treated with neuroleptic drugs (e.g., phenothiazines); hallucinations (especially visual); dizziness; muscle weakness; ataxia; dry mouth; mydriasis; blurred vision; palpitations; tachycardia; elevated blood pressure; nausea; vomiting; dysuria; numbness of fingers; dysphagia; allergic reactions, e.g., skin rash; headache; hot, dry, flushed skin; delirium; coma; shock; convulsions; respiratory arrest; anhidrosis; hyperthermia; glaucoma; constipation.

Treatment

Physostigmine salicylate, 1 to 2 mg, SC or IV, reportedly will reverse symptoms of anticholinergic intoxication. *A second injection may be given after 2 hours if required. Otherwise treatment is symptomatic and supportive. Induce emesis or perform gastric lavage (contraindicated in precoma, convulsive, or psychotic states).

Maintain respiration. A short-acting barbiturate may be used for CNS excitement, but with caution to avoid subsequent depression; supportive care for depression (avoid convulsant stimulants such as picrotoxin, pentylentetrazol, or bemegride); artificial respiration for severe respiratory depression; a local miotic for mydriasis and cycloplegia; ice bags or other cold applications and alcohol sponges for

hyperpyrexia, a vasopressor and fluids for circulatory collapse. Darken room for photophobia.

DOSAGE AND ADMINISTRATION

Benztropine Mesylate Tablets should be used when patients are able to take oral medications.

The injection is especially useful for psychotic patients with acute dystonic reactions or other reactions that make oral medication difficult or impossible. It is recommended also when a more rapid response is desired than can be obtained with the tablets.

Because of cumulative action, therapy should be initiated with a low dose which is increased gradually at five or six-day intervals to the smallest amount necessary for optimal relief. Increases should be made in increments of 0.5 mg, to a maximum of 6 mg, or until optimal results are obtained without excessive adverse reactions.

Postencephalitic and Idiopathic Parkinsonism

The usual daily dose is 1 to 2 mg, with a range of 0.5 to 6 mg orally or parenterally. As with any agent used in parkinsonism, dosage must be individualized according to age and weight, and the type of parkinsonism being treated. Generally, older patients, and thin patients cannot tolerate large doses. Most patients with postencephalitic parkinsonism need fairly large doses and tolerate them well.

Patients with a poor mental outlook are usually poor candidates for therapy.

In idiopathic parkinsonism, therapy may be initiated with a single daily dose of 0.5 to 1 mg at bedtime. In some patients, this will be adequate; in others 4 to 6 mg a day may be required.

In postencephalitic parkinsonism, therapy may be initiated in most patients with 2 mg a day in one or more doses. In highly sensitive patients, therapy may be initiated with 0.5 mg at bedtime, and increased as necessary.

Some patients experience greatest relief by taking the entire dose at bedtime; others react more favorably to divided doses, two to four times a day. Frequently, one dose a day is sufficient, and divided doses may be unnecessary or undesirable. The long duration of action of this drug makes it particularly suitable for bedtime medication when its effects may last throughout the night, enabling patients to turn in bed during the night more easily, and to rise in the morning.

When benztropine mesylate is started, do not terminate therapy with other antiparkinsonian agents abruptly. If the other agents are to be reduced or discontinued, it must be done gradually. Many patients obtain greatest relief with combination therapy.

Benztropine mesylate may be used concomitantly with the combination of carbidopa-levodopa, or with levodopa, in which case periodic dosage adjustment may be required in order to maintain optimum response.

Drug-Induced Extrapyrarnidal Disorders

In treating extrapyramidal disorders due to neuroleptic drugs (e.g., phenothiazines), the recommended dosage is 1 to 4 mg once or twice a day orally or parenterally. Dosage must be individualized according to the need of the patient. Some patients require more than recommended; others do not need as much.

In acute dystonic reactions, 1 to 2 mL of the injection usually relieves the condition quickly. After that, the tablets, 1 to 2 mg twice a day, usually prevent recurrence. When extrapyramidal disorders develop soon after initiation of treatment with neuroleptic drugs (e.g., phenothiazines), they are likely to be transient. One to 2 mg of Benztropine Mesylate Tablets two or three times a day usually provides relief within one or two days. After one or two weeks, the drug should be withdrawn to determine the continued need for it. If such disorders recur, benztropine mesylate can be reinstated.

Certain drug-induced extrapyramidal disorders that develop slowly may not respond to benztropine

mesylate.

HOW SUPPLIED

Benztropine Mesylate Tablets USP are available as:

0.5 mg: White, round, flat-faced, beveled edge, scored tablet. Debossed with stylized b over 1114 on one side and bisected on the other side. Available in blisterpacks of 30 tablets and 31 tablets.

1 mg: White, oval shaped, scored tablet. Debossed with stylized b over 1115 on one side and bisected on the other side. Available in blisterpacks of 30 tablets and 31 tablets.

2 mg: White, round, flat-faced, beveled edge, scored tablet. Debossed with stylized b over 1116 on one side and bisected on the other side. Available in blisterpacks of 30 tablets and 31 tablets.

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

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

*(Duvoisin, R.C.; Katz, R.J.; *Amer. Med. Ass.* 206: 1963-1965, Nov. 25, 1968).

TEVA PHARMACEUTICALS USA

Sellersville, PA 18960

Rev. B 1/2010

11001597

PRINCIPAL DISPLAY PANEL

VLINDC 0510-2547-38
**BENZTROPINE
 MESYLATE**
 TABS, USP 0.5 mg

LOT
 2547
 EXP
 50113930139
 10450-35

Rx
 Only

QTY
 30

MFD BY TEVA
 (SUIVA NDC
 50111-393-01)
 PKG BY VANGARD
 OLABOOK, KY 40341

Benzotropine Mesylate Tabs, USP 0.5 mg

Received: _____

STORE AT 20°-25°C (68°-77°F)
 (SEE USP CONTROLLED ROOM TEMPERATURE)
 Dispense in a light, light-resistant container.

24	16	8
31	23	7
30	22	6
29	21	5
28	20	4
27	19	3
26	18	2
25	17	1

See Package Insert Binder for Dosage Information
 FOR INSTITUTIONAL USE ONLY

30	23	15	7
29	22	14	6
28	21	13	5
27	20	12	4
26	19	11	3
25	18	10	2
24	17	9	1

Pkg By Vanguard, Shalimar, KY 40341 BENZTROPINE MESYLATE TABLET, USP 0.5 mg LOT 2547 	Pkg By Vanguard, Shalimar, KY 40341 BENZTROPINE MESYLATE TABLET, USP 0.5 mg LOT 2547 	Pkg By Vanguard, Shalimar, KY 40341 BENZTROPINE MESYLATE TABLET, USP 0.5 mg LOT 2547 	16355 Rev. 03 50111-393-01
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PRINCIPAL DISPLAY PANEL

VLI NDC 0615-2548-39
**BENZTROPINE
 MESYLATE**
 TABS, USP 1 mg

LOT
 2548
 EXP
 50113940339
 10879-39

Rx
 Only

QTY
 30

MFG BY TEVA

PKG BY VANGARD
 GLASGOW, KY 42141

(PLIVA NDC 50111-394-03)
**Benzotropine
 Mesylate**
 Tabs, USP 1 mg

Received: _____
 24 _____ 16 _____ 8 _____
 31 _____ 23 _____ 15 _____ 7 _____
 30 _____ 22 _____ 14 _____ 6 _____
 29 _____ 21 _____ 13 _____ 5 _____
 28 _____ 20 _____ 12 _____ 4 _____
 27 _____ 19 _____ 11 _____ 3 _____
 26 _____ 18 _____ 10 _____ 2 _____
 25 _____ 17 _____ 9 _____ 1 _____
 START DATE _____ START TIME _____

STORE AT 20°-25°C (68°-77°F)
 (SEE USP CONTROLLED ROOM TEMPERATURE)
 Dispense in a tight, light-resistant container.

See Package Insert Binder for Dosage Information
 FOR INSTITUTIONAL USE ONLY

	16	8
30	23	15
29	22	14
28	21	13
27	20	12
26	19	11
25	18	10
24	17	9
		1

Pkg By Vanguard, Glasgow, KY 42141 BENZTROPINE MESYLATE TABLET, USP 1 mg LOT 2548 	Pkg By Vanguard, Glasgow, KY 42141 BENZTROPINE MESYLATE TABLET, USP 1 mg LOT 2548 	Pkg By Vanguard, Glasgow, KY 42141 BENZTROPINE MESYLATE TABLET, USP 1 mg LOT 2548 	10383 Rev 00 Vanguard, Inc. Glasgow, KY 42141 
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PRINCIPAL DISPLAY PANEL

VL NDC 0515-2549-39
**BENZTROPINE
 MESYLATE**
 TABS, USP 2 mg



LOT
 2547
 EXP
 5011395039
 10448-35

Rx
 Only

QTY
 30

MFG BY TEVA
 (SUIVA NDC
 50111-395-03)
 PKG BY VANGARD
 OLABOOK, KY 42141

**Benztrapine
 Mesylate**
 Tabs, USP 2 mg

Received: _____

24	16	8
31	23	7
30	22	6
29	21	5
28	20	4
27	19	3
26	18	2
25	17	1

START DATE _____ START TIME _____

STORE AT 20°-25°C (68°-77°F)
 (SEE USP CONTROLLED ROOM TEMPERATURE)
 Dispense in a light, light-resistant container.

See Package Insert Binder for Dosage Information
 FOR INSTITUTIONAL USE ONLY

16	8	16	8	16	8	16	8	16	8
30	23	15	7	30	23	15	7	30	23
29	22	14	6	29	22	14	6	29	22
28	21	13	5	28	21	13	5	28	21
27	20	12	4	27	20	12	4	27	20
26	19	11	3	26	19	11	3	26	19
25	18	10	2	25	18	10	2	25	18
24	17	9	1	24	17	9	1	24	17



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BENZTROPINE MESYLATE

benztropine mesylate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0615-2547(NDC:50111-393)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZTROPINE MESYLATE (UNII: WMJ8TL7510) (BENZTROPINE - UNII:1NHL2J4X8K)	BENZTROPINE MESYLATE	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6IU)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	6mm
Flavor		Imprint Code	b;1114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-2547-31	31 in 1 BLISTER PACK		
2	NDC:0615-2547-39	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089058	02/28/2010	

BENZTROPINE MESYLATE

benztropine mesylate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0615-2548(NDC:50111-394)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZTROPINE MESYLATE (UNII: WMJ8TL7510) (BENZTROPINE - UNII:1NHL2J4X8K)	BENZTROPINE MESYLATE	1 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	OVAL	Size	6mm
Flavor		Imprint Code	b;1115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-2548-31	31 in 1 BLISTER PACK		
2	NDC:0615-2548-39	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089059	02/28/2010	

BENZTROPINE MESYLATE

benztropine mesylate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0615-2549(NDC:50111-395)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZTROPINE MESYLATE (UNII: WMJ8TL7510) (BENZTROPINE - UNII:1NHL2J4X8K)	BENZTROPINE MESYLATE	2 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3S5YLH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	6mm
Flavor		Imprint Code	b;1116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-2549-31	31 in 1 BLISTER PACK		
2	NDC:0615-2549-39	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089060	02/28/2010	

Labeler - NCS HealthCare of KY, Inc dba Vanguard Labs (050052943)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, Inc dba Vanguard Labs		050052943	RELABEL(0615-2547, 0615-2548, 0615-2549) , REPACK(0615-2547, 0615-2548, 0615-2549)

Revised: 2/2013

NCS HealthCare of KY, Inc dba Vanguard Labs