

**TRIHEXYPHENIDYL HYDROCHLORIDE - trihexyphenidyl hydrochloride tablet**  
**Novitium Pharma LLC**

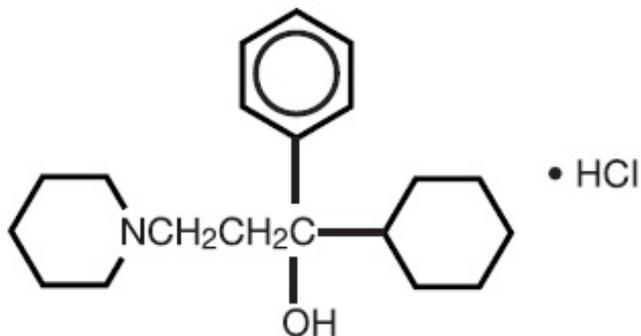
-----

**Novitium Pharma LLC.**

**TRIHEXYPHENIDYL HYDROCHLORIDE Tablets, USP 2 mg and 5 mg**  
**Rx Only**

**DESCRIPTION**

Trihexyphenidyl hydrochloride Tablets, USP is a synthetic antispasmodic drug available in the following forms: Tablets, 2 mg and 5 mg. It is designated chemically 1-Piperidinepropanol,  $\alpha$ -cyclohexyl- $\alpha$ -phenyl-, hydrochloride. The structural formula is represented below:



Trihexyphenidyl Hydrochloride Tablets, USP 2 mg and 5 mg contain the following inactive ingredients: Microcrystalline cellulose, magnesium stearate and sodium starch glycolate.

**CLINICAL PHARMACOLOGY**

Trihexyphenidyl Hydrochloride is the substituted piperidine salt, 3-(1-piperidyl)- 1-phenylcyclohexyl-1-propanol hydrochloride, which exerts a direct inhibitory effect upon the parasympathetic nervous system. It also has a relaxing effect on smooth musculature; exerted both directly upon the muscle tissue itself and indirectly through an inhibitory effect upon the parasympathetic nervous system. Its therapeutic properties are similar to those of atropine, although undesirable side effects are ordinarily less frequent and severe than with the latter.

**INDICATIONS & USAGE**

This drug is indicated as an adjunct in the treatment of all forms of parkinsonism (postencephalitic, arteriosclerotic, and idiopathic). It is often useful as adjuvant therapy when treating these forms of parkinsonism with levodopa. Additionally, it is indicated for the control of extrapyramidal disorders caused by central nervous system drugs such as the dibenzoxazepines, phenothiazines, thioxanthenes, and butyrophenones.

## **WARNINGS**

Patients to be treated with trihexyphenidyl hydrochloride should have a gonioscope evaluation and close monitoring of intraocular pressures at regular periodic intervals.

## **PRECAUTIONS**

### **GENERAL PRECAUTIONS**

Although trihexyphenidyl hydrochloride is not contraindicated for patients with cardiac, liver, or kidney disorders, or with hypertension, such patients should be maintained under close observation.

Since the use of trihexyphenidyl hydrochloride may, in some cases, continue indefinitely and since it has atropine-like properties, patients should be subjected to constant and careful long-term observation to avoid allergic and other untoward reactions. In as much as trihexyphenidyl hydrochloride possesses some parasympatholytic activity, it should be used with caution in patients with glaucoma, obstructive disease of the gastrointestinal or genitourinary tracts, and in elderly males with possible prostatic hypertrophy.

Geriatric patients, particularly over the age of 60, frequently develop increased sensitivity to the actions of drugs of this type, and hence, require strict dosage regulation. Incipient glaucoma may be precipitated by parasympatholytic drugs such as trihexyphenidyl hydrochloride.

Tardive dyskinesia may appear in some patients on long term therapy with antipsychotic drugs or may occur after therapy when these drugs have been discontinued. Antiparkinson agents do not alleviate the symptoms of tardive dyskinesia and in some instances may aggravate them. However, parkinsonism and tardive dyskinesia often coexist in patients receiving chronic neuroleptic treatment, and anticholinergic therapy with trihexyphenidyl hydrochloride may relieve some of these parkinsonism symptoms.

### **ADVERSE REACTIONS**

Minor side effects, such as dryness of the mouth, blurring of vision, dizziness, mild nausea, or nervousness, will be experienced by 30 to 50 percent of all patients. These sensations, however, are much less troublesome with trihexyphenidyl hydrochloride than with belladonna alkaloids and are usually less disturbing than unalleviated parkinsonism. Such reactions tend to become less pronounced, and even to disappear, as treatment continues. Even before these reactions have remitted spontaneously, they may often be controlled by careful adjustment of the dosage form, amount of drug, or interval between doses.

Isolated instances of suppurative parotitis secondary to excessive dryness of the mouth, skin rashes, dilatation of the colon, paralytic ileus, and certain psychiatric manifestations such as delusions and hallucinations, plus one doubtful case of paranoia all of which may occur with any of the atropine-like drugs, have been rarely reported with trihexyphenidyl hydrochloride.

Patients with arteriosclerosis or with a history of idiosyncrasy to other drugs may exhibit reactions of mental confusion, agitation, disturbed behavior, or nausea and vomiting. Such patients should be allowed to develop a tolerance through the initial administration of a small dose and gradual increase in dose until an effective level is reached. If a severe reaction should occur, administration of the drug should be discontinued for a few days and then resumed at a lower dosage. Psychiatric disturbances can result from indiscriminate use (leading to overdose) to sustain continued euphoria.

Potential side effects associated with the use of any atropine-like drugs include constipation, drowsiness, urinary hesitancy or retention, tachycardia, dilation of the pupil, increased intraocular tension, weakness, vomiting, and headache.

The occurrence of angle-closure glaucoma due to long-term treatment with trihexyphenidyl hydrochloride has been reported.

**To report SUSPECTED ADVERSE REACTIONS, contact Novitium Pharma LLC at 1-516-305-1658 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **DOSAGE & ADMINISTRATION**

Dosage should be individualized. The initial dose should be low and then increased gradually, especially in patients over 60 years of age. Whether trihexyphenidyl hydrochloride may best be given before or after meals should be determined by the way the patient reacts. Postencephalitic patients, who are usually more prone to excessive salivation, may prefer to take it after meals and may, in addition, require small amounts of atropine which, under such circumstances, is sometimes an effective adjuvant. If trihexyphenidyl hydrochloride tends to dry the mouth excessively, it may be better to take it before meals, unless it causes nausea. If taken after meals, the thirst sometimes induced can be allayed by mint candies, chewing gum or water.

### **Trihexyphenidyl Hydrochloride in Idiopathic Parkinsonism**

As initial therapy for parkinsonism, 1 mg may be administered the first day. The dose may then be increased by 2 mg increments at intervals of three to five days, until a total of 6 to 10 mg is given daily. The total daily dose will depend upon what is found to be the optimal level. Many patients derive maximum benefit from this daily total of 6 to 10 mg, but some patients, chiefly those in the postencephalitic group, may require a total daily dose of 12 to 15 mg.

### **Trihexyphenidyl Hydrochloride in Drug-Induced Parkinsonism**

The size and frequency of dose of trihexyphenidyl hydrochloride needed to control extrapyramidal reactions to commonly employed tranquilizers, notably the phenothiazines, thioxanthenes, and butyrophenones, must be determined empirically. The total daily dosage usually ranges between 5 and 15 mg, although, in some cases, these reactions have been satisfactorily controlled on as little as 1 mg daily. It may be advisable to commence therapy with a single 1 mg dose. If the extrapyramidal manifestations are not controlled in a few hours, the subsequent doses may be progressively increased until satisfactory control is achieved. Satisfactory control may sometimes be more rapidly achieved by temporarily reducing the dosage of the tranquilizer on instituting trihexyphenidyl hydrochloride therapy and then adjusting dosage of both drugs until the desired ataractic effect is retained without onset of extrapyramidal reactions.

It is sometimes possible to maintain the patient on a reduced trihexyphenidyl hydrochloride dosage after the reactions have remained under control for several days. Instances have been reported in which these reactions have remained in remission for long periods after trihexyphenidyl hydrochloride therapy was discontinued.

### **Concomitant Use of Trihexyphenidyl Hydrochloride with Levodopa**

When trihexyphenidyl hydrochloride is used concomitantly with levodopa, the usual dose of each may need to be reduced. Careful adjustment is necessary, depending on side effects and degree of symptom control. Trihexyphenidyl hydrochloride dosage of 3 to 6 mg daily, in divided doses, is usually adequate.

### **Concomitant Use of Trihexyphenidyl Hydrochloride with Other Parasympathetic Inhibitors**

Trihexyphenidyl Hydrochloride may be substituted, in whole or in part, for other parasympathetic inhibitors. The usual technique is partial substitution initially, with progressive reduction in the other medication as the dose of trihexyphenidyl hydrochloride is increased.

Trihexyphenidyl Hydrochloride Tablets - The total daily intake of trihexyphenidyl hydrochloride tablets is tolerated best if divided into 3 doses and taken at mealtimes. High doses (> 10 mg daily) may be divided into 4 parts, with 3 doses administered at meal times and the fourth at bedtime.

## HOW SUPPLIED

Trihexyphenidyl Hydrochloride Tablets, USP 2 mg are available as white, flat face, beveled edge and round. The upper layer is bisected and debossed "212/N", the lower layer is plain:

Bottle of 100's NDC 70954-212-10

Bottle of 1000's NDC 70954-212-20

Trihexyphenidyl Hydrochloride Tablets, USP 5 mg are available as white, flat face, beveled edge and round. The upper layer is bisected and debossed "211/N", the lower layer is plain:

Bottle of 100's NDC 70954-211-10

Bottle of 1000's NDC 70954-211-20

Dispense in a tight container with child-resistant closure.

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

Manufactured by:

Novitium Pharma LLC,

70 Lake Drive,

East Windsor, New Jersey-08520

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

### Trihexyphenidyl Hydrochloride Tablets, USP 2 mg 100's

NDC 70954-212-10  
**Trihexyphenidyl  
Hydrochloride  
Tablets, USP**  
**2 mg**  
Rx only  
**100 Tablets**  
novitium  
pharma

Each Tablet Contains Trihexyphenidyl Hydrochloride,  
USP .....2 mg.  
Dispense in a tight container with child-resistance closure.  
Dosage: See accompanying package insert for dosage and  
full prescribing information.  
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled  
Room Temperature].  
Manufactured by:  
Novitium Pharma LLC  
70 Lake Drive, East Windsor  
New Jersey 08520  
Issued: 02/19

3 70954 21210 2

NO VARNISH

LB4144-01

### Trihexyphenidyl Hydrochloride Tablets, USP 2 mg 1000's

NDC 70954-212-20

### Trihexyphenidyl Hydrochloride Tablets, USP

**2 mg**

Rx only  
1000 Tablets



Each Tablet Contains Trihexyphenidyl Hydrochloride, USP .....2 mg.

Dispense in a tight container with child-resistance closure.

**Dosage:** See accompanying package insert for dosage and full prescribing information.

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

Manufactured by:  
**Novitium Pharma LLC**  
70 Lake Drive, East Windsor  
New Jersey 08520

Issued: 02/19

LB4146-01



NO VARNISH

### Trihexyphenidyl Hydrochloride Tablets, USP 5 mg 100's

NDC 70954-211-10

### Trihexyphenidyl Hydrochloride Tablets, USP

**5 mg**

Rx only  
100 Tablets



Each Tablet Contains Trihexyphenidyl Hydrochloride, USP .....5 mg.

Dispense in a tight container with child-resistance closure.

**Dosage:** See accompanying package insert for dosage and full prescribing information.

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

Manufactured by:  
**Novitium Pharma LLC**  
70 Lake Drive, East Windsor  
New Jersey 08520

Issued: 02/19

LB4145-01



NO VARNISH

### Trihexyphenidyl Hydrochloride Tablets, USP 5 mg 1000's

NDC 70954-211-20

### Trihexyphenidyl Hydrochloride Tablets, USP

**5 mg**

Rx only  
1000 Tablets



Each Tablet Contains Trihexyphenidyl Hydrochloride, USP .....5 mg.

Dispense in a tight container with child-resistance closure.

**Dosage:** See accompanying package insert for dosage and full prescribing information.

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

Manufactured by:  
**Novitium Pharma LLC**  
70 Lake Drive, East Windsor  
New Jersey 08520

Issued: 02/19

LB4147-01



NO VARNISH

## TRIHXYPHENIDYL HYDROCHLORIDE

trihexyphenidyl hydrochloride tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70954-211
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TRIHEXYPHENIDYL HYDROCHLORIDE (UNII: AO61G82577) (TRIHEXYPHENIDYL - UNII:6RC5V8B7PO)	TRIHEXYPHENIDYL HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	211;N
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70954-211-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/28/2019	
2	NDC:70954-211-20	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/28/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040254	01/28/2019	

## TRIHEXYPHENIDYL HYDROCHLORIDE

trihexyphenidyl hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70954-212
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TRIHEXYPHENIDYL HYDROCHLORIDE (UNII: AO61G82577) (TRIHEXYPHENIDYL - UNII:6RC5V8B7PO)	TRIHEXYPHENIDYL HYDROCHLORIDE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

### Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	212;N
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70954-212-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/28/2019	
2	NDC:70954-212-20	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/28/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040254	01/28/2019	

**Labeler** - Novitium Pharma LLC (080301870)

### Establishment

Name	Address	ID/FEI	Business Operations
Novitium Pharma LLC		080301870	MANUFACTURE(70954-211, 70954-212) , PACK(70954-211, 70954-212)

Revised: 1/2019

Novitium Pharma LLC