Product Monograph

Including Patient Medication Information

Pr TRIHEXYPHENIDYL

Trihexyphenidyl Hydrochloride Tablets

For oral use

2 mg and 5 mg

USP

Antispasmodic

AA PHARMA INC.
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Date of Authorization:
2026-01-20

Control Number: 294364

Recent Major Label Changes

None at time of the most recent authorization

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

TRIHEXYPHENIDYL (trihexyphenidyl hydrochloride tablets) is indicated for:

- Treatment of all forms of Parkinsonism (postencephalitic, arteriosclerotic, and idiopathic).
- Prevention or control of extrapyramidal disorders due to central nervous system drugs such as reserpine and the phenothiazines.

1.1. Pediatrics

Pediatrics (<18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2. Geriatrics

Geriatrics (>60 years of age): Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness. See 4.2 Recommended dose and dosage adjustment, Geriatrics and 7.1.4 Geriatrics.

2. Contraindications

TRIHEXYPHENIDYL is contraindicated in:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition and Packaging.

4. Dosage and Administration

4.1. Dosing Considerations

- Dosage should be individualized. The initial dosage should be low and then increased gradually, especially in patients over 60 years of age.

4.2. Recommended Dose and Dosage Adjustment

Parkinsonism

1 mg orally the first day; increased by 2 mg daily at intervals of 3 to 5 days, up to 6 to 10 mg daily. The 2 mg tablets are scored therefore can be split adequately in equal halves if necessary.
Best tolerated in divided doses at mealtime.

Drug-Induced Parkinsonism

The size and frequency of doses of TRIHEXYPHENIDYL needed to control drug-induced extrapyramidal reactions, attributable especially to reserpine and phenothiazine derivatives, 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 or instituting TRIHEXYPHENIDYL therapy and then adjusting dosage of both drugs until the desired ataractic effect is retained without onset of the extrapyramidal reactions.

It is sometimes possible to maintain the patient on a reduced TRIHEXYPHENIDYL 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 therapy was discontinued.

Pediatrics (<18 years of age): Health Canada has not authorized an indication for pediatric use. See 1.1 Pediatrics.

Geriatrics (>60 years of age): Geriatric patients, especially those over the age of 60, frequently develop increased sensitivity to parasympatholytic drugs and therefore require strict dosage regulation. Treatment should be initiated at a low dose, and followed by a gradual titration. See 7.1.4 Geriatrics

Hepatic and renal impairment: No information is available for this drug product.

4.2.1 Discontinuing Treatment

Patients should be observed carefully if abrupt reduction or discontinuation of TRIHEXYPHENIDYL is required, especially if the patient is receiving neuroleptics. See 7 Warnings and Precautions, Neurologic, Neuroleptic Malignant Syndrome).

4.4 Administration

Best tolerated in divided doses at mealtime.

4.5. Missed Dose

If the patient misses a dose, instruct the patient to take the dose as soon as they remember. If it is almost time for the next dose, inform the patient to skip the missed dose and continue the regular dosing schedule.

5. Overdose

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition and Packaging

Table 1 – Dosage Forms, Strengths and Composition

Route of Administration	Dosage Form / Strength / Composition	Non-Medicinal Ingredients
Oral	Tablets 2 mg, 5 mg of trihexyphenidyl hydrochloride	Croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

Description

TRIHEXYPHENIDYL 2 mg tablet: Each white, round, flat-faced, bevelled-edge tablet, engraved score over TRM on one side, other side plain, contains 2 mg trihexyphenidyl hydrochloride. Available in bottles of 100.

TRIHEXYPHENIDYL 5 mg tablet: Each white, round, flat-faced, bevelled-edge tablet, engraved score over 5 on one side, other side plain, contains 5 mg trihexyphenidyl hydrochloride. Available in bottles of 100.

7. Warnings and Precautions

General

Patients undergoing prolonged therapy should be subjected to constant and careful long-term observation to avoid allergic and other untoward reactions.

Cardiovascular

Maintain patients with cardiac or hypertensive disorders under close observation.

Gastrointestinal

TRIHEXYPHENIDYL should be used with caution in patients with obstructive disease of the gastrointestinal tract.

Genitourinary

TRIHEXYPHENIDYL should be used with caution in patients with obstructive disease of the genitourinary tract, and in elderly males with possible prostatic hypertrophy.

Hepatic/Biliary/Pancreatic

Maintain patients with liver disorders under close observation.

Neurologic

Neuroleptic Malignant Syndrome: TRIHEXYPHENIDYL must not be withdrawn abruptly. A symptom complex resembling Neuroleptic Malignant Syndrome, including muscular rigidity, increased body temperature, mental changes (e.g., agitation, confusion, coma) and increased serum creatine phosphokinase, has been reported when anti-Parkinsonian medicinal products were withdrawn abruptly.

Rhabdomyolysis secondary to Neuroleptic Malignant Syndrome or severe dyskinesias have been observed rarely in patients with Parkinson's disease. Patients should be carefully observed when the dose of TRIHEXYPHENIDYL are abruptly reduced or discontinued, especially if the patient is receiving antipsychotics. Should a combination of such symptoms occur, the patient should be kept under medical surveillance, hospitalized if necessary, and appropriate symptomatic treatment given. This may include resumption of therapy with TRIHEXYPHENIDYL after appropriate evaluation.

Ophthalmologic

TRIHEXYPHENIDYL should be used with caution in patients with glaucoma. Incipient glaucoma may be precipitated by trihexyphenidyl hydrochloride tablets.

Renal

Maintain patients with kidney disorders under close observation.

7.1. Special Populations

7.1.1. Pregnancy

As no data were submitted and reviewed by Health Canada, the safety of TRIHEXYPHENIDYL during pregnancy cannot be established, and the potential risk is considered unknown.

7.1.2. Breastfeeding

It is unknown if trihexyphenidyl hydrochloride is excreted in human milk. Precaution should be exercised because many drugs can be excreted in human milk.

7.1.3. Pediatrics

Pediatrics (<18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4. Geriatrics

Geriatrics (>60 years of age): Geriatric patients, particularly over the age of 60, frequently develop increased sensitivity to parasympatholytic drugs and hence, require strict dosage regulation. See 4.2 Recommended Dose and Dosage Adjustment.

TRIHEXYPHENIDYL should be used with caution in elderly males with possible prostatic hypertrophy. See 7 Warnings and Precautions, Genitourinary.

Incipient glaucoma may be precipitated by trihexyphenidyl hydrochloride tablets. See 7 Warnings and Precautions, Ophtalmologic.

8. ADVERSE REACTIONS

8.1. Adverse Reaction Overview

Dryness of mouth, blurred vision, dizziness, mild nausea or nervousness will be experienced by 30 to 50% of all patients.

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, have been rarely reported with trihexyphenidyl hydrochloride tablets.

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 a 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 overdosage) to sustain continued euphoria.

Potential untoward effects associated with the use of any atropine-like drugs include the following:

Cardiac disorders: Tachycardia.

Eye disorders: Dilatation of pupils, intraocular pressure increased.

Gastrointestinal disorders: Constipation, vomiting.

General disorders and administration site conditions: Weakness.

Nervous system disorders: Drowsiness, headache.

Renal and urinary disorders: Urinary hesitancy or retention.

8.2. Clinical Trial Adverse Reactions

This information is not available for this drug product.

8.3. Less Common Clinical Trial Adverse Reactions

This information is not available for this drug product.

8.4. Abnormal Laboratory Findings: Hematologic, Clinical Chemistry, and Other Quantitative Data

This information is not available for this drug product.

8.5. Post-Market Adverse Reactions

This information is not available for this drug product.

9. Drug Interactions

9.2 Drug Interactions Overview

As no data were submitted and reviewed by Health Canada, the potential for drug interactions of TRIHEXYPHENIDYL cannot be established, and the associated risk remains unknown.

9.3 Drug-Behaviour Interactions

The interaction of TRIHEXYPHENIDYL with individual behavioural risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) is not available for this drug product.

9.4 Drug-Drug Interactions

Interactions with other drugs have not been established.

9.5. Drug-Food Interactions

Interactions with food have not been established.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1. Mechanism of Action

This information is not available for this drug product.

10.2. Pharmacodynamics

This information is not available for this drug product.

10.3. Pharmacokinetics

This information is not available for this drug product.

11. Storage, Stability and Disposal

Store at room temperature, 15-30°C (59-86°F). Preserve in tight containers.

Part 2: Scientific Information

13. Pharmaceutical Information

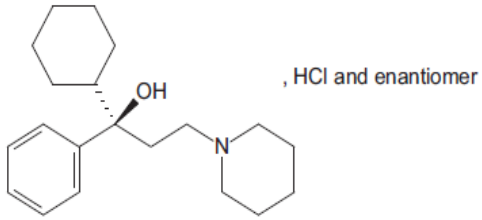
Drug Substance

Non-proprietary name of the drug substance: Trihexyphenidyl Hydrochloride

Chemical name:(1*RS*)-1-Cyclohexyl-1-phenyl-3-(piperidin-1-yl) propan-1-ol Hydrochloride

Molecular formula and molecular mass: $C_{20}H_{32}ClNO$ and 337.93 g/mol

Structural formula:



Physicochemical properties:

Appearance:	White or almost white crystalline powder.
Solubility:	Slightly soluble in Water, sparingly soluble in Ethanol (96%) and in Methylene Chloride.
Melting Point:	About 250°C.
Pharmaceutical standard:	USP-EP

14. Clinical Trials

The clinical trial data on which the original indication was authorized is not available.

15. Microbiology

No microbiological information is required for this drug product.

16. Non-Clinical Toxicology

This information is not available for this drug product.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]TRIHEXYPHENIDYL

Trihexyphenidyl Hydrochloride Tablets

This Patient Medication Information is written for the person who will be taking **TRIHEXYPHENIDYL**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **TRIHEXYPHENIDYL**, talk to a healthcare professional.

What TRIHEXYPHENIDYL is used for:

TRIHEXYPHENIDYL is used in adults to:

- treat all forms of Parkinsonism (a movement disorder).
- prevent or control movement disorders caused by certain central nervous system drugs (e.g., reserpine and phenothiazines). This includes disorders that cause extreme restlessness, involuntary movements, or muscle spasms.

How TRIHEXYPHENIDYL works:

TRIHEXYPHENIDYL belongs to a group of medicines known as “antispasmodics”. The exact way it works is not known. However, it can help with muscle control and reducing stiffness making it easier to move.

The ingredients in TRIHEXYPHENIDYL are:

Medicinal ingredient: Trihexyphenidyl hydrochloride.

Non-medicinal ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

TRIHEXYPHENIDYL comes in the following dosage form(s):

Tablets: 2 mg and 5 mg of trihexyphenidyl hydrochloride.

Do not use TRIHEXYPHENIDYL if:

- you are allergic to trihexyphenidyl hydrochloride or any of the other ingredients in TRIHEXYPHENIDYL.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRIHEXYPHENIDYL. Talk about any health conditions or problems you may have, including if you:

- have heart or blood vessel problems.
- have high blood pressure.
- have gastrointestinal (GI) tract problems.
- have liver problems.
- have kidney problems.
- have glaucoma (increased pressure in the eyes).
- have prostate problems.
- have trouble passing urine.
- are pregnant or plan to become pregnant.
- are 60 years of age or older.
- have one of the following rare genetic conditions:
    - Galactose intolerance,
    - Lapp lactase deficiency, or
    - Glucose-galactose malabsorption.

  Lactose is a non-medicinal ingredient in TRIHEXYPHENIDYL.
- are breast-feeding or plan to breast-feed. It is not known if trihexyphenidyl is passed into breast milk).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take TRIHEXYPHENIDYL:

- Always take TRIHEXYPHENIDYL exactly as your healthcare professional has told you to. Ask your healthcare professional if you are not sure.
- TRIHEXYPHENIDYL tablets should be taken at meal times (just before or just after a meal).
- Do **not** stop taking this medicine suddenly as your symptoms may get worse. If your dose needs to be lowered, your healthcare professional will reduce the amount you should take gradually.

Usual dose:

Your healthcare professional will decide the right dose and frequency for you. This may depend on your health condition, your age, and how you react to TRIHEXYPHENIDYL. You will normally start on a low dose and this may be gradually increased by your healthcare professional.

The usual dose is between 5 mg to 15 mg divided up in a day. If you are 60 years of age or older, you may need less than the usual dose.

Overdose:

If you think you, or a person you are caring for, have taken too much TRIHEXYPHENIDYL, contact a healthcare professional, hospital emergency department, or regional poison control centre, or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no symptoms.

Missed dose:

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at the regularly scheduled time.

Possible side effects from using TRIHEXYPHENIDYL:

These are not all the possible side effects you may have when taking TRIHEXYPHENIDYL. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of TRIHEXYPHENIDYL may include:

- dizziness,
- drowsiness
- dry mouth,
- feeling weak and tired,
- headache,
- nervousness.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Very Common			
Eye problems: dilated pupils, light sensitivity changes, increased pressure in the eyes, eye and head pain, swelling or redness in or around the eye, changes in vision, hazy or blurred vision, or sudden sight loss.		**X**	
Rare			
Gastrointestinal (GI) tract problems: stomach pain, stomach discomfort, bloating, constipation, nausea, vomiting, loss of appetite, unable to pass gas or stool, cramps, or feeling dehydrated.	**X**		
Mental and/or behavioural changes: confusion, agitation, aggression, defiant behaviour, loss of sleep, restlessness, delusions (a false belief, despite incontrovertible evidence, that something is false), hallucinations (seeing or hearing things that are not there), or paranoia (unrealistic and excessive anxiety, worry, distrust and suspicion).		**X**	
Skin rashes	**X**		
Unknown			
Angle-closure glaucoma (increased pressure in the eyes): vision changes, blurred vision, halos around lights, seeing rainbows around the eyes, sudden loss		**X**	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
of sight, eye pain, eye redness, nausea, vomiting, or severe headache.			
Kidney and urinary problems: difficulty peeing, trouble starting or slow urine flow, or unable to completely empty the bladder.		**X**	
Neuroleptic malignant syndrome (a serious drug reaction): muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion, reduced consciousness, increased breathing rate, or change in blood pressure.			**X**
Tachycardia (abnormally fast heartbeat)		**X**	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax;
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store TRIHEXYPHENIDYL at room temperature, 15°C to 30°C. Preserve in a tight container.

Keep out of reach and sight of children.

If you want more information about TRIHEXYPHENIDYL:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (https://www.aapharma.ca/en/), or by calling 1-877-998-9097.

This leaflet was prepared by AA Pharma Inc., 1165 Creditstone Road Unit #1, Vaughan, Ontario, L4K 4N7

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