PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

[Pr] HYDROXYZINE HYDROCHLORIDE INJECTION USP

Hydroxyzine Hydrochloride

Solution, 50 mg/mL, for Intramuscular administration

USP

Anxiolytic - Sedative

Sandoz Canada Inc.

110 rue de Lauzon
Boucherville, Québec, Canada
J4B 1E6

Date of Initial Authorization:
APR 27, 1987

Date of Revision:
MAY 11, 2022

Submission Control Number: 256978

RECENT MAJOR LABEL CHANGES

2 CONTRAINDICATIONS	05/2022
4 DOSAGE AND ADMINISTRATION, 4.1 Dosing Considerations	05/2022
5 OVERDOSAGE	05/2022
7 WARNINGS AND PRECAUTIONS	05/2022

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

HYRDOXYZINE HYDROCHLORIDE INJECTION USP (hydroxyzine hydrochloride) is indicated for:

- the symptomatic alleviation of pathological anxiety in patients with psychoneurotic disorders
- the alleviation of acutely disturbed psychoneurotic patients
- the alleviation of excessive anxiety and tension prior to surgical procedures
- the reduction in narcotic dosage and controls emesis, when used as pre and postoperative medication
- the symptomatic management of patients with acute alcoholic withdrawal

1.1 Pediatrics

Pediatrics (0 to 18 years of age): Health Canada has not authorized an indication for pediatric use. See 4.2 Recommended Dose and Dosage Adjustment, Pediatrics.

1.2 Geriatrics

Geriatrics: Evidence from experience suggests that use in the geriatric population is associated with differences in safety or effectiveness.

2 CONTRAINDICATIONS

HYRDOXYZINE HYDROCHLORIDE INJECTION USP is contraindicated:

- In patients who are hypersensitive to hydroxyzine hydrochloride, cetirizine, other piperazine derivatives, aminophylline or ethylenediamine 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.
- In patients with history of QT prolongation and/or torsade de pointes, including congenital long QT syndromes; history of cardiac arrhythmias; significant electrolyte imbalance (hypokalemia, hypomagnesium); significant bradycardia; family history of sudden cardiac death. See 7 WARNINGS AND PRECAUTIONS, Cardiovascular
- With concomitant use of other QT/QTc-prolonging drugs. See 7 WARNINGS AND PRECAUTIONS, Cardiovascular; 9.4 Drug-Drug Interactions.
- With concomitant use of CYP3A4/5 inhibitors (See 7 WARNINGS AND PRECAUTIONS, Cardiovascular; 9.4 Drug-Drug Interactions; 9.5 Drug-Food Interactions).
- In asthmatics who have previously experienced a serious anti-histamine induced adverse bronchopulmonary effect.
- In patients with porphyria.
- In women of childbearing potential and early pregnancy.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- Hydroxyzine should also be administered cautiously to epileptic patients.
- In order to help mitigate the potential risk of QT interval prolongation HYDROXYZINE should be used for as short a duration as possible, at the lowest effective dose up to specified maximums. See 2 CONTRAINDICATIONS; 4.2 Recommended Dose and Dosage Adjustment; 7 WARNINGS AND PRECAUTIONS, Cardiovascular; 9.4 Drug-Drug Interactions.

4.2 Recommended Dose and Dosage Adjustment

The dosage should be individualized and adjusted in accordance with tolerance and the patient's response to therapy.

Symptomatic use for alleviation of excessive anxiety should usually be limited to periods of one week.

Adults: The maximum total daily dose in adults is 100 mg, given in divided doses.

Pediatrics:

- Not recommended in children under 6 years of age.
- In children and adolescents up to 40 kg in weight, the maximum daily dose is 2 mg /kg /day, given in divided doses. (Therefore, at the maximum weight of 40 kg, the maximum daily dose is 80 mg).
- In children and adolescents over 40 kg, the maximum daily dose is the same as for adults: 100 mg per day, given in divided doses.

Geriatrics: Use should generally be avoided, but if judged to be an appropriate option in an individual case, the maximum daily dose is 50 mg, given in divided doses.

Hepatic impairment: The total daily dose should be reduced by 33%. Use in patients with severe liver impairment should be avoided.

Renal impairment: For patients with moderate or severe renal impairment, the total daily dosage should be reduced by 50%.

4.4 Administration

- HYDROXYZINE HYDROCHLORIDE INJECTION USP is intended only for intramuscular administration and should not, under any circumstances, be injected subcutaneously, intra-arterially, or intravenously.
- HYDROXYZINE HYDROCHLORIDE INJECTION USP should be injected well within the body of a relatively large muscle such as the upper outer quadrant of the buttocks or the lateral thigh. Inadvertent subcutaneous injection may result in significant tissue damage. See 7 WARNINGS AND PRECAUTIONS, Skin.

5 OVERDOSAGE

QT prolongation and torsade de pointes have been observed with excessive blood concentrations of hydroxyzine in a context of overdose or impaired drug metabolism. Electrocardiogram monitoring is recommended in the event of overdosage.

Close monitoring of patient and symptomatic management.

Hypotension, though unlikely, may be controlled with intravenous fluids and vasopressors (such as norepinephrine). Do not use epinephrine as HYDROXYZINE HYDROCHLORIDE INJECTION USP counteracts its pressor action. There is no specific antidote. It is doubtful that hemodialysis would be of any value in the treatment of overdosage with hydroxyzine. However, if other agents have been ingested concomitantly, hemodialysis may be indicated.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular	Solution, Hydroxyzine Hydrochloride 50 mg / mL	Benzyl Alcohol, Sodium hydroxide, Water for Injection

Hydroxyzine Hydrochloride Injection USP, 50 mg/mL, is available in single use amber ampoules of 1 mL, boxes of 10.

7 WARNINGS AND PRECAUTIONS

General
Because of its potential antimuscarinic actions, HYDROXYZINE HYDROCHLORIDE INJECTION USP should be used with caution in patients suffering from angle closure glaucoma, urinary retention, prostatic hyperplasia, or pyloroduodenal obstruction.

Concomitant Use with CNS depressants: In view of its sedative properties, hydroxyzine may potentiate the effects of other central nervous system depressants such as sedatives, hypnotics, narcotics, non-narcotic analgesics, barbiturates, psychotropic agents and alcohol. Patients should be cautioned not to drink alcohol while taking hydroxyzine and reductions in the dosages may be required if hydroxyzine is used in conjunction with other central nervous system depressants. See 9.4 Drug-Drug Interactions.

Cardiovascular
Caution is required in patients with cardiovascular disease and hypertension.

Hydroxyzine has been associated with QT/QTc interval prolongation. Rare events of torsade de pointes,

cardiac arrest, and sudden death have been reported with hydroxyzine during post-market use.

Torsade de pointes is a polymorphic ventricular tachyarrhythmia. Generally, the risk of torsade de pointes increases with the magnitude of QT/QTc prolongation produced by the drug. Torsade de pointes may be asymptomatic or experienced by the patient as dizziness, palpitations, syncope, or seizures. If sustained, torsade de pointes can progress to ventricular fibrillation and sudden cardiac death.

Particular care should be exercised when administering hydroxyzine to patients who are suspected to be at an increased risk of experiencing torsade de pointes during treatment with a QT/QTc-prolonging drug. Risk factors for torsade de pointes in the general population include, but are not limited to, the following:

- female gender;
- age 65 years or older;
- baseline prolongation of the QT/QTc interval;
- presence of genetic variants affecting cardiac ion channels or regulatory proteins, especially congenital long QT syndromes;
- family history of sudden cardiac death at <50 years;
- cardiac disease (e.g., myocardial ischemia or infarction, congestive heart failure, left ventricular hypertrophy, cardiomyopathy, conduction system disease);
- history of arrhythmias (especially ventricular arrhythmias, atrial fibrillation, or recent conversion from atrial fibrillation);
- electrolyte disturbances (e.g., hypokalemia, hypomagnesemia, hypocalcemia) or conditions leading to electrolyte disturbances (e.g., gastrointestinal disease, eating disorders);
- bradycardia (<50 beats per minute);
- acute neurological events (e.g., intracranial or subarachnoid haemorrhage, stroke, intracranial trauma);
- diabetes mellitus;
- autonomic neuropathy.

When drugs that prolong the QT/QTc interval are prescribed, healthcare professionals should counsel their patients concerning the nature and implications of the ECG changes, underlying diseases and disorders that are considered to represent risk factors, demonstrated and predicted drug-drug interactions, symptoms suggestive of arrhythmia, risk management strategies, and other information relevant to the use of the drug. See 2 CONTRAINDICATIONS; 4.1 Dosing Considerations; 9.4 Drug-Drug Interactions; 9.5 Drug-Food Interactions.

Driving and Operating Machinery

Since hydroxyzine may produce sedation and drowsiness, patients should be warned against driving or operating dangerous machinery while taking hydroxyzine.

Endocrine and Metabolism

Caution is required in patients with hyperthyroidism.

Gastrointestinal

Caution is required in patients with decreased GI motility and stenosing peptic ulcer.

Hepatic/Biliary/Pancreatic

Use in patients with severe liver impairment should be avoided.

For patients with other liver impairment, dose reduction is required. See 4.2 Recommended dose and Dosage Adjustment.

Neurologic

Caution is required in patients with myasthenia gravis, dementia and seizure disorders, including epilepsy.

Ophthalmologic

Caution is required in patients with increased intraocular pressure.

Reproductive Health: Female and Male Potential

- **Fertility**

No data is available on the effects of hydroxyzine hydrochloride on fertility.

Renal

Caution is required in patients with bladder outflow obstruction.

For patients with moderate or severe renal impairment, dose reduction is required. See 4.2 Recommended dose and Dosage Adjustment.

Respiratory

Caution is required in patients with breathing problems (e.g. emphysema, chronic bronchitis).

Skin

Inadvertent subcutaneous injection may result in significant tissue damage. See 4.4 Administration.

Acute Generalized Exanthematous Pustulosis (AGEP): Hydroxyzine may rarely cause acute generalized exanthematous pustulosis (AGEP), a serious skin reaction characterized by fever and numerous small, superficial, nonfollicular, sterile pustules, arising within large areas of edematous erythema. Inform patients about the signs of AGEP, and discontinue hydroxyzine at the first appearance of a skin rash, worsening of pre-existing skin reactions which hydroxyzine may be used to treat, or any other sign of hypersensitivity. If signs or symptoms suggest AGEP, use of hydroxyzine should not be resumed and alternative therapy should be considered. Avoid cetirizine or levocetirizine in patients who have experienced AGEP or other hypersensitivity reactions with hydroxyzine, due to the risk of cross-sensitivity.

7.1 Special Populations

7.1.1 Pregnant Women

HYDROXYZINE HYDROCHLORIDE INJECTION USP (hydroxyzine hydrochloride) is contraindicated in early pregnancy. See 2 CONTRAINDICATIONS.

Hydroxyzine hydrochloride, when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic range. Clinical data in human beings are inadequate to establish safety in early pregnancy.

7.1.2 Breast-feeding

It is unknown if HYDROXYZINE HYDROCHLORIDE INJECTION USP is excreted in human milk. Since many drugs are excreted in human milk, HYDROXYZINE HYDROCHLORIDE INJECTION USP should not be given to nursing mothers.

7.1.3 Pediatrics

Pediatrics (0 to 18 years of age): Health Canada has not authorized an indication for pediatric use. See 4.2 Recommended Dose and Dosage Adjustment, Pediatrics.

8 ADVERSE REACTIONS

HYDROXYZINE HYDROCHLORIDE INJECTION USP may cause sedation, drowsiness and impairment of mental alertness which tend to disappear in a few days of continued therapy or upon reduction of the dose. Anticholinergic activity, including dryness of the mouth have been reported. Involuntary movements, including tremor and convulsions have also occurred. Rarely, blood dyscrasias have been reported.

8.5 Post-Market Adverse Reactions

Cardiac disorders: Rare cases of cardiac arrest, cardio-respiratory arrest, electrocardiogram QT prolonged, and torsade de pointes, some fatal, have been reported following the use of hydroxyzine-containing products.

Immune system disorders: allergic reaction.

Nervous system disorders: headache.

Psychiatric disorders: hallucination.

Skin and subcutaneous tissue disorders: pruritus, rash, urticaria.

9 DRUG INTERACTIONS

9.1 Serious Drug Interactions

Serious Drug Interactions

QT/QTc-prolonging drugs
Concomitant use of HYDROXYZINE with another QT/QTc prolonging drug is contraindicated as it may result in QT/QTc prolongation. See 2 CONTRAINDICATIONS; 9.4 Drug-Drug Interactions.

CYP3A4/5 inhibitors
Concomitant use of HYDROXYZINE with CYP3A4/5 inhibitors is contraindicated as it may result in increased blood level of HYDROXYZINE and in QT/QTc prolongation. See 2 CONTRAINDICATIONS; 9.4 Drug-Drug Interactions; 9.5 Drug-Food Interactions.

9.3 Drug-Behavioural Interactions

HYDROXYZINE HYDROCHLORIDE INJECTION USP may product additive CNS depressant effects when co-administered with alcohol. See 7 WARNINGS AND PRECAUTIONS, General, Concomitant Use with CNS depressants.

9.4 Drug-Drug Interactions

CNS depressants: HYDROXYZINE HYDROCHLORIDE INJECTION USP may potentiate the effects of other central nervous system depressants. See 7 WARNINGS AND PRECAUTIONS, General, Concomitant Use with CNS Depressants.

QT/QTc-Prolonging Drugs: The concomitant use of hydroxyzine with another QT/QTc prolonging drug is contraindicated. Drugs that have been associated with QT/QTc interval prolongation and/or torsade de pointes include, but are not limited to, the examples in the following list. Chemical/pharmacological classes are listed if some, although not necessarily all, class members have been implicated in QT/QTc prolongation and/or torsade de pointes:

- Class IA antiarrhythmics (e.g., quinidine, procainamide, disopyramide);
- Class III antiarrhythmics (e.g., amiodarone, sotalol, ibutilide);
- Class 1C antiarrhythmics (e.g., flecainide, propafenone);
- antipsychotics (e.g., chlorpromazine, pimozide, haloperidol, droperidol, ziprasidone, risperidone, olanzapine);
- antidepressants (e.g., fluoxetine, citalopram, venlafaxine, tricyclic/tetracyclic antidepressants e.g., amitriptyline, imipramine, maprotiline). See 7 WARNINGS AND PRECAUTIONS, General, Concomitant Use with CNS depressants);
- opioids (e.g., methadone);
- macrolide antibiotics and analogues (e.g., erythromycin, clarithromycin, azithromycin, tacrolimus);
- quinolone antibiotics (e.g., moxifloxacin, levofloxacin, ciprofloxacin);
- pentamidine;

- antimalarials (e.g., quinine, chloroquine);
- azole antifungals (e.g., ketoconazole, fluconazole, voriconazole);
- domperidone;
- 5-hydroxytryptamine (5-HT3) receptor antagonists (e.g.,ondansetron);
- arsenic trioxide
- tyrosine kinase inhibitors (e.g., vandetanib, sunitinib, nilotinib);
- histone deacetylase inhibitors (e.g., vorinostat);
- beta-2 adrenoceptor agonists (e.g., salmeterol, formoterol).

Drugs that Cause Electrolyte Depletion: The use of hydroxyzine with drugs that can disrupt electrolyte levels is not recommended. Such drugs include, but are not limited to, the following:

- loop, thiazide, and related diuretics;
- laxatives and enemas;
- amphotericin B;
- high dose corticosteroids

CYP3A4/5 Inhibitors: Hydroxyzine is a substrate for CYP3A4/5. Plasma levels of hydroxyzine can be increased by inhibitors of CYP3A4/5. Prolongation of the QT/QTc interval by hydroxyzine is anticipated to be increased in the presence of CYP3A4/5 inhibitors. Drugs that inhibit CYP3A4/5 include, but are not limited to, certain azole antifungals, macrolide antibiotics, and HIV protease inhibitors. The concomitant use of these drugs with hydroxyzine is contraindicated. See 2 CONTRAINDICATIONS.

The above lists of potentially interacting drugs are not comprehensive. Current information sources should be consulted for newly approved drugs that prolong the QT/QTc interval, inhibit CYP3A4/5, or cause electrolyte disturbances, as well as for older drugs for which these effects have recently been established.

9.5 Drug-Food Interactions

CYP3A4 can be inhibited by certain foods, including, but not limited to, grapefruit, grapefruit juice, and grapefruit-containing products, which could lead to increased plasma concentrations of hydroxyzine. Patients should be instructed not to consume these foods during treatment with hydroxyzine because the risk of QT/QTc prolongation may be increased. See 7 WARNINGS AND PRECAUTIONS, Cardiovascular; 9.4 Drug-Drug Interactions.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Treatment should be stopped for one week before skin testing for allergy is undertaken, and for 96 hours prior to a methacholine test.

10 CLINICAL PHARMACOLOGY

Hydroxyzine is an antihistamine with anticholinergic, antiemetic and sedative properties.

11 STORAGE, STABILITY AND DISPOSAL

Temperature:
Store between 15 and 30°C.

Light:
Protect from light.

12 SPECIAL HANDLING INSTRUCTIONS

None.

PART II: SCIENTIFIC INFORMATION

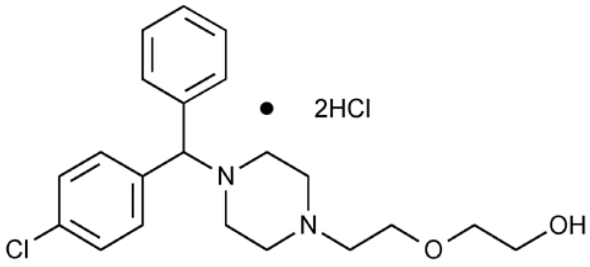
13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Hydroxyzine Hydrochloride

Molecular formula and molecular mass: C21H27ClN2O2·2HCl, 447.83 g/mol

Structural formula:



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

Information not available.

PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Hydroxyzine Hydrochloride Injection USP
Hydroxyzine hydrochloride

Read this carefully before you start taking **HYDROXYZINE HYDROCHLORIDE INJECTION USP** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **HYDROXYZINE HYDROCHLORIDE INJECTION USP**.

What is HYDROXYZINE HYDROCHLORIDE INJECTION USP used for?

HYDROXYZINE HYDROCHLORIDE INJECTION USP is used:

- to reduce anxiety and/or agitation in patients with certain psychiatric conditions
- to reduce excess anxiety and tension before surgical procedures
- to reduce the dosage of pain killers and to control vomiting before and after surgery
- management of symptoms of alcohol withdrawal

How does HYDROXYZINE HYDROCHLORIDE INJECTION USP work?

HYDROXYZINE HYDROCHLORIDE INJECTION USP belongs to a group of drugs called antihistamines. It works by calming the brain and nerves.

What are the ingredients in HYDROXYZINE HYDROCHLORIDE INJECTION USP?

Medicinal ingredients: hydroxyzine hydrochloride

Non-medicinal ingredients: Benzyl Alcohol, Sodium hydroxide, Water for Injection

HYDROXYZINE HYDROCHLORIDE INJECTION USP comes in the following dosage forms:

As a 50 mg / mL solution.

Do not use HYDROXYZINE HYDROCHLORIDE INJECTION USP if:

- you are allergic to hydroxyzine hydrochloride or to any of the other ingredients in HYDROXYZINE HYDROCHLORIDE INJECTION USP (See **What are the ingredients in HYDROXYZINE HYDROCHLORIDE INJECTION USP?**).
- you are allergic to other medicines called piperazine derivatives or the medicines certizine, aminophylline and ethylenediamine.
- you have had an ECG (electrocardiogram) that showed that you have or have had a heart rhythm problem called "QT interval prolongation" or other problems with your heart rhythm.
- you are taking other medicines that have an effect on heart rhythm.
- you have or have had heart disease.
- you have or have had a heart rate that is very slow.
- you have had anyone in your family die suddenly from heart problems.
- you have low levels of potassium or magnesium in your blood.
- you have asthma and have had an allergic reaction to another antihistamine in the past.
- you have porphyria (a rare inherited disease where there is a problem with proteins in the blood).

- you can become pregnant and are not taking birth-control, are pregnant or planning to become pregnant.

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

- have kidney problems or are on dialysis.
- have liver problems or liver failure.
- have glaucoma or increased pressure in the eye.
- have digestive problems, such as ulcers or inflammation of the stomach or esophagus, pyloroduodenal obstruction, or decreased gastrointestinal motility.
- have myasthenia gravis (a muscle weakness disorder).
- have dementia.
- have lung or breathing problems such as: emphysema or chronic bronchitis.
- have trouble emptying your bladder.
- have prostate problems.
- have thyroid problems or an "overactive thyroid".
- have high blood pressure (hypertension).
- are dehydrated, suffer from excessive vomiting or diarrhea or have an eating disorder.
- have recently had a stroke, bleeding in your brain or any other head trauma.
- have diabetes.
- are breast-feeding
- have autonomic neuropathy (a dysfunction of the nerves)

Other warnings you should know about:

Serious heart problems: HYDROXYZINE HYDROCHLORIDE INJECTION USP may cause serious heart problems, such as worsening of the health of your heart, heart rhythm disorders (QT prolongation), cardiac arrest and sudden death.

If you have any of the following symptoms while you are taking HYDROXYZINE HYDROCHLORIDE INJECTION USP, stop taking it and get immediate medical help:

- dizziness
- heart palpitations (feeling of rapid pounding or skipped heartbeat or "fluttering")
- fainting
- seizures

See the **Serious side effects and what to do about them** table, below for information on this and other serious side effects.

Test results: HYDROXYZINE HYDROCHLORIDE INJECTION USP may affect allergy and asthma tests. If you are scheduled to have allergy or asthma tests stop taking HYDROXYZINE HYDROCHLORIDE INJECTION USP:

- 1 week before a skin test for allergies
- 96 hours before a methacholine test (a test to diagnose asthma)

Driving and Using Machines: HYDROXYZINE HYDROCHLORIDE INJECTION USP may make you drowsy. Avoid driving or operating machinery or doing tasks that require special attention.

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

Serious Drug Interactions

Do not take HYDROXYZINE HYDROCHLORIDE INJECTION USP with medicines/foods that can affect:

- **your heart rhythm or**
- **increase your blood levels of hydroxyzine**

as this may cause:

- worsening of the health of your heart
- heart rhythm disorders (QT prolongation)
- cardiac arrest
- death

Examples of these medications/foods include, but are not limited to:

- heart medicines used to treat abnormal heart rhythm such as quinidine, amiodarone
- medicines used to treat mental health problems such as haloperidol
- depressants such as citalopram, amitriptyline
- tricyclic antidepressants such as amitriptyline, imipramine, maprotiline
- opioid medication such as methadone
- antibiotics used to treat bacterial infections such as erythromycin, ciprofloxacin
- antimalarial medicines such as quinine, chloroquine
- medicines used to treat fungal infections such as ketoconazole
- domperidone, used to speed up the movements of the stomach and bowel
- nausea and vomiting such as ondansetron
- cancer such as arsenic trioxide, vandetanib, tremifene
- breathing problems like asthma and chronic obstructive pulmonary discorder (COPD) such as salmeterol, formoterol)
- treat HIV/AIDS (protease inhibitors)
- fungal infections such as ketoconazole
- grapefruit, grapefruit juice and grapefruit-containing products

The following may interact with HYDROXYZINE HYDROCHLORIDE INJECTION USP:

- alcohol. Do not drink alcohol while you are taking HYDROXYZINE HYDROCHLORIDE INJECTION USP.
- medicines used to treat allergies, such as antihistamines
- medicines used to treat seizures or epilepsy (anticonvulsants)
- medicines that can have an effect on brain function. This medicine is used to treat mental illnesses or behavioural problems such as depression, anxiety, attention or mood problems, and psychosis
- other sedatives
- drugs of recreational use
- Medications that can cause low levels of electrolytes in your blood such as:
    - medicines used to relieve constipation (laxatives and enemas)
    - high dose corticosteroids, used to treat swelling and inflammation

- medicines used to help your body get rid of water (diuretics), also called "water pills", used to treat high blood pressure
- medicines used to treat fungal infections

How to take HYDROXYZINE HYDROCHLORIDE INJECTION USP:

- HYDROXYZINE HYDROCHLORIDE INJECTION USP will be given to you by a healthcare professional. It will be injected into your muscle.

Usual dose:

Adults: The maximum daily dose is 100 mg, given in divided doses.

Geriatrics (> 65 years of age): HYDROXYZINE should be avoided in the elderly. If HYDROXYZINE has been recommended by your healthcare professional, the maximum daily dose for the elderly is 50 mg per day, given in divided doses.

Patients with liver problems: Your healthcare professional may reduce your dose.

Patients with kidney problems: Your healthcare professional may reduce your dose.

Overdose:

If you think you, or a person you are caring for, have taken too much HYDROXYZINE HYDROCHLORIDE INJECTION USP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

HYDROXYZINE HYDROCHLORIDE INJECTION USP will be given to you in a healthcare setting. Your healthcare professional will make sure you do not miss a dose.

What are possible side effects from using HYDROXYZINE HYDROCHLORIDE INJECTION USP?

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

Side effects may include:

- Dry mouth
- Flushing
- Drowsiness
- Headache
- Itching
- Rash

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
UNCOMMON			

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Allergic reactions: rash, hives, swelling of the lips, tongue, face or throat, difficulty breathing or swallowing.			✓
Heart problems: feeling lightheaded, dizzy or passing out (fainting), irregular heartbeat or heart palpitations (skipped beats), cardiac arrest (heart stops beating).			✓
Seizures: loss of consciousness with uncontrollable shaking.			✓
Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose eyes and genitals and spread to other areas of the body, swelling of face and/or legs, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine.			✓
UNKNOWN FREQUENCY			
Hallucinations: seeing or hearing things that are not really there			✓

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

Stored between 15 and 30°C and protect from light.

Keep out of reach and sight of children.

If you want more information about HYDROXYZINE HYDROCHLORIDE INJECTION USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.sandoz.ca, or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

Last Revised MAY 11, 2022.