PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

[Pr]**ATARAX**

Hydroxyzine Hydrochloride Oral Solution USP

Syrup, 10 mg/5 ml, Oral

USP

Anxiolytic – Antihistamine agent

Searchlight Pharma Inc.
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Date of Initial Authorization:
OCT 11, 2022

Submission Control No.: 267154

RECENT MAJOR LABEL CHANGES

7 Warnings and Precautions, Skin	05/2022

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

ATARAX (hydroxyzine hydrochloride) is indicated in adults for:

- Management of anxiety
- Pre-medication, such as preparation for dental procedures.
- Management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses.
- Control of nausea and vomiting, excluding nausea and vomiting of pregnancy (see 2 CONTRAINDICATIONS).

1.1 Pediatrics

ATARAX is indicated in children for:

- Pre-medication, such as preparation for dental procedures.
- Management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses.
- Control of nausea and vomiting, excluding nausea and vomiting of pregnancy (see 2 CONTRAINDICATIONS)

1.2 Geriatrics

Evidence from clinical experience suggests that use in the geriatric population is associated with differences in safety or efficacy.

2 CONTRAINDICATIONS

ATARAX 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, hypomagnesemia); 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 early (first trimester) pregnancy

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

In order to help mitigate the potential risk of QT interval prolongation, ATARAX 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

Adults:

- The maximum total daily dose in adults is 100 mg (50 mL), given in divided doses.

Children and Adolescents:

- 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 or 40 mL).
- In children and adolescents over 40 kg, the maximum daily dose is the same as for adults: 100 mg per day (50 mL), given in divided doses.

Geriatric:

- Use should generally be avoided, but if judged to be an appropriate option in an individual case, the maximum daily dose in geriatric patients is 50 mg (25 mL), 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%.

4.5 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 OVERDOSAGE

The most common manifestation of ATARAX overdosage is hypersedation. Other reported signs and symptoms were convulsions, stupor, nausea and vomiting. QT prolongation and torsade de pointes have been observed with excessive blood concentrations of hydroxyzine in a context of overdose or impaired drug metabolism. As in the management of overdosage with any drug, ingestion of multiple agents may have occurred.

General supportive care, including frequent monitoring of the vital signs and close observation of the patient, is indicated. Electrocardiogram monitoring is recommended in the event of overdosage.

Hypotension, though unlikely, may be controlled with intravenous fluids and vasopressors (such as norepinephrine). Do not use epinephrine as ATARAX 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 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Oral	Syrup 10 mg hydroxyzine hydrochloride per 5 mL	Alcohol, menthol, peppermint oil, sodium benzoate (1.5 mg per 5 mL), spearmint oil, sucrose, water. Sodium hydroxide or hydrochloric acid (for pH adjustment) Energy: 67 kJ (16 kcal) Tartrazine-free

ATARAX : Available in bottles of 473 mL.

7 WARNINGS AND PRECAUTIONS

General

Because of its potential anticholinergic actions, ATARAX should be used with caution in patients with the following conditions:

- angle-closure glaucoma
- increased intraocular pressure
- urinary retention
- bladder outflow obstruction
- prostatic hyperplasia
- pyloroduodenal obstruction
- stenosing peptic ulcer
- decreased GI motility
- myasthenia gravis
- dementia
- breathing problems (e.g. emphysema, chronic bronchitis)
- hyperthyroidism
- cardiovascular disease
- hypertension

Concomitant use with CNS depressants

The potentiating action of hydroxyzine hydrochloride must be considered when the drug is used in conjunction with central nervous system (CNS) depressants such as narcotics, non-narcotic analgesics, hypnotics, sedatives, psychotherapeutic agents, barbiturates or alcohol. Therefore when central nervous

system depressants are administered concomitantly with ATARAX their dosage should be reduced (see 9.4 Drug-Drug Interactions).

Cardiovascular

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 postmarket 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 also 2 CONTRAINDICATIONS; 4.1 Dosing Considerations; 9.4 Drug-Drug Interactions; 9.5 Drug-Food Interactions).

Driving and Operating Machinery

Since drowsiness may occur with use of this drug, patients should be cautioned against driving a car or operating dangerous machinery while taking ATARAX .

Neurologic

ATARAX should be used with caution in patients with seizure disorders, including epilepsy.

Skin

Acute Generalized Exanthematous Pustulosis
Hydroxyzine may rarely cause acute generalized exanthematous pustulosis (AGEP), a serious skin reaction characterized by fever and numerous small, superficial, non-follicular, 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

ATARAX 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 not known whether this drug is excreted in human milk. Since many drugs are so excreted, ATARAX should not be given to nursing mothers.

7.1.3 Pediatrics

Based on the data submitted and reviewed by Health Canada, the safety and efficacy of ATARAX in pediatric patients has been established. Therefore, Health Canada has authorized an indication for pediatric use. See 1.1 Pediatrics.

7.1.4 Geriatrics

See 4.2 Recommended Dose and Dosage Adjustment; 7 WARNINGS AND PRECAUTIONS, Cardiovascular.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Side effects reported with the administration of ATARAX are usually mild and transitory in nature.

Gastrointestinal disorders: Dry mouth may be encountered at higher dosages.

Nervous system disorders: Drowsiness

Involuntary motor activity, including rare instances of tremor and convulsions, has been reported, usually with doses considerably higher than those recommended.

8.5 Post-Market Adverse Reactions

In post-marketing experience, the following additional undesirable effects have been reported:

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 ATARAX and QT/QTc-prolonging drugs is contraindicated as it may result in QT/QTc prolongation.

CYP3A4/5 inhibitors
Concomitant use of ATARAX and 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

ATARAX may produce 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

QT/QTc-Prolonging Drugs: The concomitant use of hydroxyzine with another QT/QTc-prolonging drug is contraindicated (see 2 CONTRAINDICATIONS). 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);
• 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-HT)3 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).

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).

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

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.

CNS depressant drugs: ATARAX may potentiate the effects of other central nervous system depressant drugs (see 7 WARNINGS AND PRECAUTIONS, General, Concomitant Use with CNS Depressants).

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.

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

Information is not available.

11 STORAGE AND STABILITY

Store at controlled room temperature (15°C – 30°C). Protect from freezing.

Keep out of reach and sight of children.

12 SPECIAL HANDLING INSTRUCTIONS

Not applicable.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

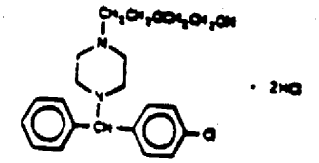
Drug Substance

Proper name: Hydroxyzine hydrochloride

Chemical name: 1-(p-chlorobenzhydryl) 4-2-(2-hydroxy-ethoxy)-ethylpiperazine dihydrochloride

Molecular formula and molecular mass: $C_{21}H_{27}ClN_2O_2$ + 2HCl, 447.83

Structural formula:



Physicochemical properties: M.p. 196 °C to 204 °C with decomposition. Soluble 1 in 1 of water, 1 in 4.5 of alcohol and 1 in 13 of chloroform, slightly soluble in acetone. Energy: 67kJ (16kcal). Tartrazine-free.

Pharmaceutical standard: USP

Product Characteristics:

Hydroxyzine hydrochloride is a white odorless powder with bitter taste.

14 CLINICAL TRIAL

The clinical trial data on which the original indications were authorized is not available.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

The non-clinical toxicology data is not available.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]ATARAX

hydroxyzine hydrochloride oral solution USP

Read this carefully before you start taking **ATARAX** 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 **ATARAX** .

What is ATARAX used for?

ATARAX is used:

In Adults:

- to help manage anxiety

In Adults and children:

- as a pre-surgery medication (such as in preparation for a dental procedure)
- in the treatment of itching with rash or eczema that is caused by an allergic reaction
- in the treatment of nausea and vomiting (such as from chemotherapy or after surgery)

How does ATARAX work?

ATARAX works by:

- blocking a substance called histamine. Your body produces this when you have an allergic reaction.
- affecting how certain chemicals work in your brain, such as serotonin.

What are the ingredients in ATARAX ?

Medicinal ingredients: hydroxyzine hydrochloride

Non-medicinal ingredients: alcohol, menthol, peppermint oil, sodium benzoate, spearmint oil, sucrose, water.

Sodium hydroxide or hydrochloric acid (for pH adjustment).

Tartrazine-free.

ATARAX comes in the following dosage forms:

Syrup, 2 mg/mL

Do not use ATARAX if:

- you are allergic to:
  - hydroxyzine hydrochloride

    - cetirizine
    - other piperazine derivatives
    - aminophylline
    - ethylenediamine
- you are allergic to any of the non-medicinal ingredients in ATARAX , or component of the container (see: “What are the ingredients in ATARAX ?”)
- you have had an ECG (electrocardiogram) that showed that you have or had a heart rhythm problem called “QT interval prolongation’’ or other problems with you heart rhythm.
- you are taking other medicines that have an effect on heart rhythm.
- you have or had heart disease
- you have or had a heart rate that is very slow
- you have had anyone in your family die suddenly from heart problems
- you have a 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 are pregnant or planning to become pregnant

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ATARAX . 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 an increased pressure in the eye
- have digestive system or stomach 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 seizure disorders including epilepsy
- have lung or breathing problems such as:
    - emphysema
    - 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)
- if you are 65 years or older

Other warnings you should know about:

Serious heart problems: Taking ATARAX 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 ATARAX , stop taking ATARAX 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: ATARAX may affect the test results of an allergy and asthma tests. If you are scheduled to have allergy or asthma tests, stop taking ATARAX :

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

Driving and Using Machines: ATARAX 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.

The following may interact with ATARAX :

Serious Drug Interactions

Do not take ATARAX with medicines/foods that can:

- **affect your heart rhythm**
- **increase your blood levels of ATARAX SYRUP 2MG/mL**

as this may cause:

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

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

- heart medicines used to treat abnormal heart rhythm (e.g. quinidine, amiodarone)
- medicines used to treat schizophrenia and other mental health problems (e.g. haloperidol)
- antidepressants (e.g. citalopram) and tricyclic antidepressants (e.g. amitriptyline)
- opioids (e.g. methadone)
- antibiotics used to treat bacterial infections (e.g. erythromycin, ciprofloxacin)
- antimalarial medicines (e.g. quinine, chloroquine)
- medicines used to treat fungal infections (e.g. ketoconazole)
- domperidone, used to speed up the movements of the stomach and bowel
- other medicines used to treat nausea and vomiting (e.g. ondansetron)

- medicines used to treat cancer (e.g. arsenic trioxide, sunitinib)
- medicines used to treat breathing problems like asthma and COPD (e.g. salmeterol, formoterol)
- medicines used to treat HIV/AIDS (protease inhibitors)
- grapefruit, grapefruit juice and grapefruit-containing products

- 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
- Alcohol. Do not drink alcohol while you are taking ATARAX . It may increase the sedative effects of the alcohol.
- Medicines used to treat seizures or epilepsy (anticonvulsants)
- Sedatives used to treat anxiety and sleeping problems
- Sedative antihistamines, used to treat allergies
- Drugs of recreational use

How to take ATARAX :

- Always take ATARAX exactly as your healthcare professional tells you to. Do not change your dose without talking to your healthcare professional.
- Your healthcare professional will ensure the lowest effective dose of ATARAX is used for the shortest amount of time.

Usual dose:

Adults: the maximum daily dose is 100 mg (50 mL), given in divided doses throughout the day.

Children and Adolescents who are **over** 40 kg in weight: the maximum daily dose is 100 mg (50 mL), given in divided doses throughout the day.

Children and Adolescents **up to** 40 kg in weight: the maximum daily dose is 2 mg/kg, given in divided doses throughout the day. Your healthcare professional will decide on the correct dose based on your child's weight.

Geriatric patients (> 65 years of age)
ATARAX should generally be avoided in the geriatric population. If ATARAX has been recommended by your healthcare professional, the maximum daily dose for the elderly is 50 mg (25 mL), given in divided doses throughout the day.

Patients with liver problems
Your healthcare professional will reduce your dose by about 1/3 if you have liver problems.

Patients with kidney problems
Your healthcare professional will reduce your dose by about 1/2 if you have kidney problems.

Overdose:

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

Symptoms of an overdose can vary and may include:

- enlarged pupils of the eye
- uncontrolled and fast eye movements
- nausea and vomiting
- slurred speech
- feeling restless
- uncontrolled or slow movements
- problems with your vision
- fast or pounding heartbeat
- seizures
- shaking
- hallucinations
- feeling unusually drowsy
- slowing of your breathing and heart rate
- losing consciousness
- hot dry skin
- fever
- problems with coordination
- confused or disturbed thinking

Missed Dose:

If you forget to take a dose, you should take it as soon as you remember. If it is close to the time of your next dose when you remember, skip the missed dose and take your next dose at the usual time. DO NOT take a double dose.

What are possible side effects from using ATARAX ?

These are not all the possible side effects you may have when taking ATARAX . 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			
Allergic reactions: rash, hives, swelling of the lips, tongue, face or throat , difficulty breathing or swallowing			✓
Heart rhythm problems : feeling lightheaded, dizzy, or passing out (fainting), irregular heartbeat or heart palpitations (skipped beats)			✓
Seizures: uncontrollable shaking with or without loss of consciousness			✓
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, talk to 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.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:

Store at controlled room temperature (15°C – 30°C). Protect from freezing.

Keep out of reach and sight of children.

If you want more information about ATARAX :

- 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.searchlightpharma.com, or by calling 1-647-945-9762.

This leaflet was prepared by Searchlight Pharma Inc.

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