



PATIENT INFORMATION LEAFLET

Atarax™ Tablets hydroxyzine hydrochloride

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

- 1. What Atarax is and what it is taken for**
- 2. Check before you take Atarax**
- 3. How to take Atarax**
- 4. Possible side effects**
- 5. How to store Atarax**
- 6. Further information**

1. What Atarax is and what it is used for

Atarax belongs to a group of medicines called antihistamines (used to treat allergic reactions). It is used in adults and children to reduce itching caused by urticaria (nettle rash) and dermatitis (eczema).

Atarax is also used to treat anxiety in adults.

2. Check before you take Atarax

Do not take Atarax

- if you are allergic (hypersensitive) to hydroxyzine hydrochloride or any of the ingredients of Atarax (see Section 6 Further information)
- if you are trying to become pregnant or are in the early stages of pregnancy.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Atarax.

Take special care with Atarax

Before you take Atarax tell your doctor if:

- you have kidney disease or are on dialysis
- you have difficulty passing water e.g. due to an enlarged prostate.

Your doctor will reduce your dose by about half if you have kidney disease.

If the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Atarax.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines as they may interfere with Atarax or Atarax may increase the effects of these medicines:

- barbiturates such as sodium amytal or phenobarbitol, used to treat sleeping disorders and epilepsy
- other CNS depressants, these include: sedatives, tranquillisers, anti-anxiety medicines (such as diazepam and temazepam) and medicines that help you sleep (such as zolpidem, chlormethiazone and buspirone).

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

Taking with food and drink

You should not take alcohol with Atarax because the sedative effects of the alcohol may be increased.

Pregnancy and breast-feeding

Do not take Atarax if you are pregnant, trying to become pregnant or breast-feeding. If you become pregnant whilst taking Atarax tell your doctor immediately.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Atarax may make you drowsy and make you feel less alert than usual for the first few days after you start taking it. If you are affected do not drive or operate machinery until this effect has worn off.

Important information about some of the ingredients of Atarax

Atarax contains lactose, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Atarax

Always take Atarax exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

The usual dose for each condition is given below:

For treating itching in adults and elderly

The starting dose is 25mg at night, your doctor may increase the dose up to 25mg three or four times daily.

For treating itching in children

The dose of Atarax depends on the age of the child:

Children aged 6 months to 6 years:

5mg to 15mg daily which your doctor may increase up to 50mg daily, taken throughout the day.

Children over 6 years:

15mg to 25mg daily which your doctor may increase up to 50mg -100mg daily, taken throughout the day.

For treating anxiety in adults

The dose is 50mg to 100mg four times a day.

For treating anxiety in children

Atarax is not suitable for treating anxiety in children.

For patients with kidney disease

Your doctor will reduce your dose by about half if you have kidney disease.

What to do if you take more Atarax than you should

You probably need not worry if you have taken an extra dose of Atarax by mistake, but if you, or someone else have taken a large overdose you should tell your doctor or contact the nearest accident and emergency department immediately. Show any leftover medicines or the empty packet to the doctor.

Atarax can cause considerable sedation that requires treatment. If any other medicines or substances have been taken at the same time as Atarax tell the medical staff carrying out the treatment of the overdose.

If you forget to take Atarax

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then go on as before.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Do not worry. Like all medicines, Atarax can cause side effects, although not everyone gets them. Atarax can cause the following side effects in some people:

- drowsiness during the first few days of treatment, this usually disappears as treatment continues
- feeling giddy
- weakness
- headache
- confusion
- dryness of the mouth.

Rarely, you may suffer more serious side effects, tell your doctor immediately if you get any of the following:

- tremor (shakiness)
- convulsions (fits)
- you have difficulty passing water.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Atarax

Keep out of the reach and sight of children.

Do not take Atarax after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What is in Atarax?

The active ingredient in this medicine is hydroxyzine hydrochloride.

The other ingredients are:

Calcium phosphate, lactose, magnesium stearate, maize starch, silicon dioxide and sodium lauryl sulphate.

The 10mg tablet coating contains Opadry® II Orange 85G23730. This is a mixture of Poly(vinyl alcohol), Talc, Macrogol 3350, Sunset yellow (E110), Titanium dioxide (E171), Iron oxide yellow (E172), Quinoline yellow (E102), Lecithin (E322).

The 25mg tablet coating contains Opadry® II Green 85G21674. This is a mixture of Poly(vinyl alcohol), Talc, Macrogol 3350, Quinoline yellow (E104), Titanium dioxide (E171), Brilliant blue (E133), Indigo carmine (E132), Lecithin (E322).

What Atarax looks like and contents of the pack

Atarax 10mg film-coated tablets are coloured orange imprinted with 'AX' on one side.

Atarax 25mg film-coated tablets are coloured green imprinted with 'AX' on one side.

Atarax tablets are supplied in blister packs contained in a carton. The 10mg tablet contains either 84 or 280 tablets and the 25mg tablet contains 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The product licence holder is: Alliance Pharmaceuticals Ltd, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Atarax is manufactured by: Recipharm Limited, Vale of Bardsley, Ashton-under-Lyne, Lancashire, OL7 9RR, UK.

The information in this leaflet applies only to Atarax. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was that was last approved in: October 2008.

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