

VOXYZINE HYDROXYZINE HCl FILM COATED TABLET

Hydroxyzine hydrochloride 10 mg
Hydroxyzine hydrochloride 25 mg

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What Voxyzine is used for

Voxyzine belongs to a group of medicines called anxiolytic (used to relieve anxiety). This medication is recommended in:

- Minor manifestations of anxiety in adults,
- As premedication before general anesthesia (loss of sensation to prevent pain),
- Pruritus (itching of the skin),
- The treatment of certain insomnia in children over 6 years old.

How Voxyzine works

Voxyzine belongs to a group of medicines called sedating antihistamines. It suppresses certain functions in the brain without creating a habit. It also blocks histamine, a substance found in body tissues. It is effective against anxiety and itching.

Before you use Voxyzine

- When you must not use it

Do not take Voxyzine:

- If you are allergic (hypersensitive) to hydroxyzine hydrochloride, cetirizine, other

piperazine derivatives, aminophylline or ethylenediamine, or any of the ingredients of Voxyzine.

- If your ECG (electrocardiogram) shows a heart rhythm problem called "QT interval prolongation".
- If you have or had a cardiovascular disease or if your heart rate is very low.
- If you have low salt levels in your body (e.g. low level of potassium or of magnesium).
- If you are taking certain medicines for heart rhythm problems or medicines that may affect the heart rhythm.
- If anyone in your close family has died suddenly of heart problems.
- If you are an asthmatic who has suffered a bad reaction to an antihistamine in the past.
- If you have porphyria (a disease which causes stomach pain, constipation, changes in the colour of urine, skin rashes and disturbed behaviour).
- If you are pregnant, trying to become pregnant or breast-feeding.
- Voxyzine 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. If you have hereditary galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption you should not take this medicine.

If any of the above applies to you, or if you are not sure, speak to your

doctor or pharmacist before you take Voxyzine.

- Before you start to use it

You need to tell your doctor if you suffer with:

- Kidney disease or are on dialysis.
- Liver disease. Voxyzine is not suitable for patients with severe liver disease or liver failure.
- Glaucoma (increased pressure in the eye).
- Difficulty passing water e.g. due to an enlarged prostate.
- Digestive system or stomach problems.
- Myasthenia gravis (a muscle weakness disorder).
- Dementia.
- Seizure disorders including epilepsy (fits).
- Breathing problems.
- Bladder outflow obstruction.
- Hyperthyroidism (often referred to as an "overactive thyroid").
- Hypertension (high blood pressure).

Your doctor may adjust your dose if you are elderly.

Voxyzine may affect the results of some tests for allergy or asthma.

Always tell your doctor or nurse that you have been given Voxyzine recently.

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

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- Taking other medicines

You should tell your doctor if you are taking any medicines as it may interact with Voxyzine.

Do not take Voxyzine if you are taking medicine to treat:

- Bacterial infections (e.g. erythromycin, moxifloxacin, levofloxacin).
- Fungal infections (e.g. pentamidine).
- Heart problems or high blood pressure (e.g. amiodarone, quinidine, disopyramide, sotalol).
- Psychoses (e.g. haloperidol).
- Depression (e.g. citalopram, escitalopram).
- Gastro-intestinal disorders (e.g. prucalopride).
- Allergy.
- Malaria (e.g. mefloquine).
- Cancer (e.g. toremifene, vandetanib).
- Drug abuse or severe pain (methadone).

It is also important that you tell your doctor if you are taking any of the following medicines:

- Adrenaline or epinephrine.
- Barbiturates (for sleeping disorders and epilepsy).
- Cimetidine (for ulcers and heartburn).
- Antiemetics (drugs effective against vomiting and nausea).
- Betahistine (used to treat a condition called Ménière's disease).
- Anaesthetics.
- Muscle relaxants.
- Opioids (medicines for relieving severe pain).
- Anticholinergic medicines, these include some medicines

used for irritable bowel syndrome, asthma or incontinence.

- Aminophylline (for breathing problems).
- Benzylpenicillin salts and chloramphenicol sodium succinate (antibiotics).
- Doxorubicin hydrochloride (a chemotherapy drug).
- Antidepressants, including monoamine oxidase inhibitors (MAOIs) (such as isocarboxazid or moclobemide), and tricyclics (such as amitriptyline).
- Medicines to treat anxiety.
- Medicines that help you sleep.
- Benzodiazepines.
- Anticholinesterase medicines (such as edrophonium and neostigmine).
- Antimuscarinic medicines (such as atropine).
- Antiepileptic medicines.
- Other antihistamines.

How to use Voxyzine

- How much to use

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

Voxyzine should be used at the lowest effective dose and the treatment period should be as short as possible.

The tablet is not a form suitable for children under 6 years old (risk of misdirection).

The recommended dose:

In adults, the maximum daily dose is 100 mg per day.

For treating itching in adults:

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

For treating anxiety in adults:

The dose is 50 mg daily, taken as 12.5 mg in the morning, 12.5 mg at noon, and 25 mg in the evening. The doctor may adjust the evening dose if needed.

Premedication for general anaesthesia in adults:

The dose is 100 mg daily.

For treating itching in children:

In children up to 40 kg in weight, the maximum daily dose is 2 mg/kg/day. In children over 40 kg, the maximum dose is 100 mg/day.

Children aged 6 and over:

The recommended dose is 1 mg/kg/day up to 2 mg/kg/day in divided doses.

Sleep problems (difficulty falling asleep) in children over 6 years:

The usual recommended dose is 1 mg/kg/per day. This medicine should only be used for a short period of time, for up to 2 weeks maximum.

For other indications in children aged 6 to 15 years:

The recommended dose is 1 mg/kg/day, depending on age and weight.

For patients with liver failure:

Your doctor will reduce your dose by about half if you have liver failure. Always take this medicine exactly as instructed in this leaflet or as directed by your doctor or

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pharmacist. Check with your doctor or pharmacist if in doubt.

For patients with kidney failure:

If you have kidney failure, ask your doctor for advice; if necessary, you will need to take a lower dose. The appropriate dosage will be determined by your doctor.

For elderly patients:

In the elderly, the maximum daily dose is 50 mg per day.

- When to use it

Your doctor will decide when it is appropriate for you to use Voxyzine according to the type of condition you have.

- How long to use it

Follow recommendations and advice from your doctor.

Voxyzine should be used at the lowest effective dose and the treatment period should be as short as possible.

- If you forget to use it

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.

- If you use too much (overdose)

If you have used or taken too much Voxyzine, immediately contact your doctor or the nearest accident and emergency department, in particular if a child has taken too much. In the event of overdose, symptomatic treatment could be implemented. An ECG monitoring could be

undertaken, because of the possibility of a heart rhythm problem such as QT interval prolongation or Torsade de Pointes.

Symptoms of an overdose can vary and may include:

- Slowing of your thoughts, slurred speech and experiencing restless, involuntary, or slow movements.
- Dry mouth, problems with your vision, fast or pounding heartbeat, difficulty passing water and constipation.
- Slowing down of your central nervous system, which can slow your breathing and heart rate, cause you to feel drowsy or become unconscious. Or you may experience stimulation of your central nervous system, with feelings of excitement, fits, shaking and hallucinations.

Voxyzine can cause considerable sedation that requires treatment.

If any other medicines or substances have been taken at the same time as Voxyzine tell the medical staff carrying out the treatment of the overdose.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Voxyzine.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take any other medicines, whether they require a prescription or not, without first

telling your doctor or consulting with a pharmacist.

- Do not stop taking the medicine unless advised by your doctor.
- Do not give this medicine to anyone else, even if they have the same symptoms or condition as you.
- Do not take Voxyzine with alcohol because the sedative effect of the alcohol may be increased.

- Things to be careful of

- Follow the dosage as recommended.

Side effects

Like all medicines, Voxyzine can cause side effects, although not everyone gets them.

If you get any of the following symptoms after taking Voxyzine, stop taking the medicine and seek immediate medical attention:

- Symptoms of a severe allergic reaction such as:
 - Swelling of the face, tongue, or throat
 - Difficulties in swallowing
 - Hives and difficulties in breathing
- Severe reactions that can include serious blistering of the skin as well as the eyes, mouth, and genitals.
- Tremor (shakiness) or convulsions (fits).
- If you experience any problems with the heart rhythm such as palpitations, trouble breathing or loss of consciousness.

Other possible side effects of Voxyzine include:

- Drowsiness, sedation, coma, slurred speech, slowing of

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- thought processes and movements, involuntary movements, dizziness, faintness, headache, inability to concentrate, sleep disturbances, bitter taste in mouth.
- Confusion, hallucinations, disorientation, unusual mood changes.
 - Bloodshot eyes, blurred vision, and difficulty in focusing.
 - Faster or pounding heartbeat.
 - Low blood pressure, flushing.
 - Dryness of the nose, mouth or throat, wheezing.
 - Liver problems (symptoms include jaundice).
 - Difficulty or pain when passing water, blood in urine.
 - Tiredness, general feeling of being unwell, fever, chills, muscle pain, chest tightness, achy joints.
 - Porphyria (a rare illness which affects the metabolism), anorexia.
 - Blood disorders.
 - Skin rashes, swelling, itching, hives, eczema, increased sweating, hair loss, tingling, prickling, numbing of skin, pus-filled skin sores.
 - Prolonged penile erection, impotence, early menstruation.
 - Hearing, balance, or coordination problems.
 - Digestive system or stomach problems, feeling or being sick, diarrhoea, constipation.
 - Weight increased (frequency unknown).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my

[Consumers → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Voxyzine

- Storage

Do not take Voxyzine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Store at temperature below 30°C. Keep out of reach of children.

- Disposal

Voxyzine should be disposed when your doctor or pharmacist tells you to stop taking this product or it has passed the expiry date. It should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose medicines that are no longer required. These measures will help to protect the environment.

Product description

- What it looks like

Voxyzine Hydroxyzine HCl Film Coated Tablet 10 mg:
A yellow color film coated round tablet.



Voxyzine Hydroxyzine HCl Film Coated Tablet 25 mg:
A white color film coated oblong tablet, one side with a score.



- Ingredients

Active Ingredients
Hydroxyzine hydrochloride

Inactive ingredients

Tablet core

Lactose Monohydrate
Microcrystalline Cellulose
Croscarmellose Sodium
Colloidal Silicon Dioxide
Magnesium Stearate

Film coating

Voxyzine Hydroxyzine HCl Film Coated Tablet 10 mg:
Hydroxypropyl methylcellulose
Polyethylene Glycol
Dimethylpolysiloxane
Iron Oxide Yellow

Voxyzine Hydroxyzine HCl Film Coated Tablet 25mg:
Hydroxypropyl methylcellulose
Polyethylene Glycol
Dimethylpolysiloxane

- MAL number:

MAL25106022AZ (10mg)
MAL25106021AZ (25mg)

Manufacturer and Product Registration Holder

Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5, 7, 12 & 14, Jln. P/7, Sec. 13,
Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

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