

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

HYDROXYZINE 25 EQUITY film-coated tablet

Hydroxyzine hydrochloride

Contains sugar (69,80 mg lactose anhydrous per tablet)

Read all of this leaflet carefully before you start using HYDROXYZINE 25 EQUITY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.
- HYDROXYZINE 25 EQUITY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What HYDROXYZINE 25 EQUITY is and what it is used for
2. What you need to know before you use HYDROXYZINE 25 EQUITY
3. How to use HYDROXYZINE 25 EQUITY
4. Possible side effects
5. How to store HYDROXYZINE 25 EQUITY
6. Contents of the pack and other information

1. What HYDROXYZINE 25 EQUITY is and what it is used for

HYDROXYZINE 25 EQUITY belongs to a group of medicines named tranquillisers and antihistamines. It is used for short-term (not more than 4 months) management of anxiety and tension (psychomotor agitation) in adults and children over 40 kg bodyweight.

HYDROXYZINE 25 EQUITY is also useful for alleviating the signs of anxiety and tension prior to dental and other minor surgeries.

HYDROXYZINE 25 EQUITY has been used as adjunctive therapy in allergic conditions with strong emotional overlay, as in hives and itchy skin conditions in adults and children over 40 kg bodyweight.

2. What you need to know before you use HYDROXYZINE 25 EQUITY

Do not use HYDROXYZINE 25 EQUITY:

- if you are hypersensitive (allergic) to hydroxyzine hydrochloride or any of the ingredients of HYDROXYZINE 25 EQUITY (listed in section 6).
- If you are allergic to medicine called cetirizine (antihistamine), aminophylline (asthma medicine), or to ethylenediamine (ingredient of aminophylline and topical skin products).
- if you have heart palpitations, shortness of breath or chest pain (QT interval prolongation).
- if you have a known risk factors for the above heart condition including heart or circulatory system disorders, electrolyte imbalances (low kalium or magnesium levels) and family history of cardiac deaths, or a slower than usual heartbeat.
- if you are taking any other medicine which could affect your heartbeat (see Other medicines and Hydroxyzine 25 Equity below).
- If you have asthma and previously experienced serious breathing problems with the use of antihistamines (hay fever medication).
- If you have rapid breathing, confusion, restlessness, inability to breath (respiratory failure).
- If you suffer from disorders resulting from build-up of certain chemicals related to red blood cell proteins (porphyria).
- If you are pregnant or breastfeeding.

Warnings and precautions

Special care should be taken with HYDROXYZINE 25 EQUITY if you:

- have a heart disorder/disease.
- have a severe liver disorder or liver failure.
- have impaired kidney function.
- are elderly; the use of HYDROXYZINE 25 EQUITY is not recommended.

- have increased eye pressure or an eye condition called closed-angle glaucoma.
- have a condition in which your bladder doesn't empty completely even if it's full (urinary retention); or if you have obstruction of your bladder
- have prostate gland enlargement that can cause urination difficulty (prostatic hyperplasia)
- have obstruction of your stomach outlet (pyrodoodenal) or a stomach ulcer
- suffer from epilepsy (seizures)
- have a neuromuscular junction disorder that causes weakness in the skeletal muscles (myasthenia gravis)
- suffer from memory loss, problem-solving and other thinking abilities that are severe enough to interfere with daily life (dementia)
- have decreased movement of your bowels
- have breathing problems
- have ever had thyroid problems (overactive thyroid gland)
- have high blood pressure (hypertension)

Stop taking HYDROXYZINE 25 EQUITY if you develop improper beating of the heart, whether irregular, too fast or too slow (signs of cardiac dysrhythmia) and seek immediate medical attention.

The use of alcohol with HYDROXYZINE 25 EQUITY should be avoided.

You may experience impaired judgment, and a decreased ability of performing skills with your hands.

Other medicines and HYDROXYZINE 25 EQUITY

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

HYDROXYZINE 25 EQUITY should not be used with the following medicine

- medicines for an uneven heartbeat (such as quinidine, disopyramide, amiodarone or sotalol)
- medicines used for hay fever, rashes or other allergies called antihistamines

- medicines for schizophrenia (such as haloperidol)
- some medicines for depression (such as citalopram or escitalopram)
- medicines for malaria (such as mefloquine)
- antibiotic (such as erythromycin, levofloxacin or moxifloxacin)
- medicines used in cancer treatment (such as toremifene or vandetanib)
- methadone.

HYDROXYZINE 25 EQUITY should with caution with the following medicine

- medicine belonging to the following sedative classes:
 - Barbiturates (phenobarbital)
 - Benzodiazepines (alprazolam, diazepam, lorazepam)
 - Medicine to assist with sleeping disorders (zolpidem)
 - Strong pain killers (Opioids e.g. codeine, morphine)
 - Medicine treating depression, nausea and vomiting, epilepsy, other allergy medicine, muscle relaxants, medicine used for anaesthesia.
- medicine belonging to a group called anticholinergic medicine e.g., atropine, oxybutynin, solifenacin
- medication called betahistine (treat the symptoms of Ménière's disease)
- indigestion/stomach ulcer medicine called cimetidine
- aminoglycoside antibiotics e.g., kanamycin, tobramycin, gentamicin, neomycin, streptomycin
- medicines that help prevent blood clots, e.g., rivaroxaban, dabigatran, warfarin.

HYDROXYZINE 25 EQUITY should not be taken at least 96 hours prior to you taking a lung test to determine your lung function (asthma test).

HYDROXYZINE 25 EQUITY should not be taken at least a week prior to skin testing for allergies.

HYDROXYZINE 25 EQUITY with food, drink and alcohol

HYDROXYZINE 25 EQUITY should not be used with alcohol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

HYDROXYZINE 25 EQUITY should not be used if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent HYDROXYZINE 25 EQUITY may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which HYDROXYZINE 25 EQUITY affects you.

HYDROXYZINE 25 EQUITY causes dizziness, disorientation, and sedation. It will affect your ability to drive or operate machinery.

HYDROXYZINE 25 EQUITY contains lactose anhydrous

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking HYDROXYZINE 25 EQUITY.

3. How to use HYDROXYZINE 25 EQUITY

Do not share medicines prescribed for you with any other person.

Always use HYDROXYZINE 25 EQUITY exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine how many tablets you should take depending on your diagnosis and your age.

Your doctor will start you on the lowest effective dose and for the shortest possible duration.

Adults

The usual adult dose ranges from 25 mg to 100 mg daily in divided doses.

The maximum daily dose of 100 mg should not be exceeded.

Children over 40 kg in weight

In children and adolescents over 40 kg in weight, the maximum daily dose is 100 mg per day in divided doses.

The usual dose for children over 40 kg in weight, starts at 15-25 mg and increase to 50-100 mg daily in divided doses adjusted according to the child's weight. Maximum daily dose in children up to 40 kg in bodyweight is 2 mg/kg/day.

Your doctor will tell you how long your treatment with HYDROXYZINE 25 EQUITY will last. If you have the impression that the effect of HYDROXYZINE 25 EQUITY is too strong or too weak, tell your doctor or pharmacist

If you take more HYDROXYZINE 25 EQUITY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

You will experience the following symptoms when you take more HYDROXYZINE 25 EQUITY than you should: depression, lack of muscle control or coordination, excitement, seizures, tremors, severe mental disorders, hallucinations, convulsions and fever can occur. Coma and loss of heart function that can be fatal may follow.

If you forget to take HYDROXYZINE 25 EQUITY

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

HYDROXYZINE 25 EQUITY can have side effects.

Not all side effects reported for HYDROXYZINE 25 EQUITY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HYDROXYZINE 25 EQUITY, please consult your health care provider for advice.

If any of the following happens, stop taking HYDROXYZINE 25 EQUITY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- skin rash or itching
- fainting
- improper beating of the heart, whether irregular, too fast or too slow (signs of cardiac dysrhythmia)

These are all very serious side effects. If you have them, you may have had a serious reaction to HYDROXYZINE 25 EQUITY. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome.
- difficulty breathing or tightness in the chest, coughing which will not go away, wheezing, weight loss and fever. This could be due to inflammation of your lungs which can be very dangerous.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Blood disorders that cause fever, chills, fast heart rate and breathing, low blood pressure, muscle weakness and fatigue, sore mouth and throat, sweating,
- Porphyria (a group of disorders that result from a build-up of natural chemicals that produce porphyrin in your body)
- An eating disorder causing people to obsess about weight and what they eat.
- Agitation, confusion, disorientation, hallucinations, sleep disturbances, depression, increased anxiety, nightmares
- Involuntary movement that you cannot control (head, arms, legs or entire body)

- Tiredness, drowsiness, dizziness, weakness, headache, tremor, convulsions, “pins and needles” feeling, coma, disturbance in attention, lack of muscle control, slurred speech, bitter taste in mouth, faintness
- Blurred vision
- Ringing or other noises in one or both ears, balance disturbances
- Heart palpitations
- Low blood pressure, flushing
- Constipation, dryness of the mouth, nausea, vomiting, diarrhoea, stomach pain
- Liver condition in which the skin, whites of the eyes and mucous membranes turn yellow
- Skin inflammation (dermatitis and eczema), rash, sweating increased, red itchy welts, hair loss, skin peeling and blistering, extreme sensitivity of the skin to light
- A distinctive type of skin medicine reaction that characteristically recurs in the same locations upon re-exposure to the offending medicine
- Muscle pain
- Difficulty urinating and completely emptying the bladder; discomfort when urinating
- Persistent, usually painful, erection; sexual dysfunction, early periods
- A general sense of being unwell; a state of physical or mental weariness; irritability, chills.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of HYDROXYZINE 25 EQUITY.

5. How to store HYDROXYZINE 25 EQUITY

Store all medicines out of reach of children.

This medicine does not require any special storage conditions.

Store in the blisters in the original container until required to use.

6. Contents of the pack and other information

What HYDROXYZINE 25 EQUITY contains

- The active substance in DOWYTAB is 25mg hydroxyzine hydrochloride.
- The other ingredients are lactose anhydrous, microcrystalline cellulose PH 112, colloidal anhydrous silica, magnesium stearate, Opadry white OY-58900 consisting of hypromellose, titanium dioxide and macrogol 400.

What HYDROXYZINE 25 EQUITY looks like and contents of the pack

Hydroxyzine 25 mg scored film-coated tablets are off-white to white, oblong, biconvex filmcoated tablets with score line on both sides.

HYDROXYZINE 25 EQUITY scored film-coated tablets are packed into the following packs:

Alu/PVC and Al/PVC/PVDC blister strips. The blister strips are packed in a cardboard box.

Pack sizes: 28, 30 & 84; 100 film-coated tablets.

Holder of Certificate of Registration

Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive, Route 21 Corporate Park

Nellmapius Drive

Irene, Gauteng

Tel: +27 (12) 345 1747

Registration number

56/2.6/0508

An electronic copy of the translated Professional Information (PI) is available on the Equity website:

<http://www.equitypharmaceuticals.co.za>