

TERRA-ZINE / Trifluoperazine Hydrochloride 1 & 5 mg tablets

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE. KEEP THIS LEAFLET UNTIL YOU HAVE FINISHED ALL THE PRESCRIBED COURSE OF TERRA-ZINE. IF YOU HAVE ANY QUESTIONS CONCERNING YOUR MEDICINE ASK YOUR DOCTOR OR PHARMACIST FOR MORE INFORMATION.

What is in Terra-zine tablets?

The active ingredient of Terra-zine is trifluoperazine hydrochloride BP.

Terra-zine 1 mg tablets contain trifluoperazine hydrochloride BP 1.18 mg.

Terra-zine 5 mg tablets contain trifluoperazine hydrochloride BP 5.90 mg.

Terra-zine 1 mg and 5 mg are both dark green sugar coated tablets

The tablets contain the following inactive ingredients; lactose, starch, pregelatinised maize starch, magnesium stearate, shellac, talc, titanium dioxide (E171), sucrose, povidone, opalux (trade name) as F-5922, beeswax, carnauba wax.

Both strengths of Terra-zine are available in containers of 28, 30, 50, 56, 60, 84, 100, 250, 500, & 1000 tablets.

The name and address of the Product Licence holder is: Chelonia Healthcare Ltd, 11 Boumpoulinas. Nicosia P.C.1060. Cyprus.

The Manufacturer of Terra-zine is:

DDSA Pharmaceuticals Ltd., Chatfield Road, off York Road, London SW11 3SE.

The active ingredient in Terra-zine tablets, trifluoperazine, belongs to a group of drugs known as phenothiazines.

Why have you been prescribed Terra-zine?

Used to help in the control of short-term anxiety, agitation, excitement, impulsive/violent behaviour, and uncontrolled bodily shaking.

Also used in the management of the symptoms of schizophrenia, and other more serious psychological disorders (paranoia, mania, hypomania).

If you are not sure why you have been prescribed Terra-zine, then please ask your doctor.

Before taking your medicine.

Before taking this medicine, tell your doctor if any of the following apply:

- If you have experienced unusual or allergic reactions in the past to other drugs belonging to the same

phenothiazine group as this medicine.

- If you have ever had liver, heart, kidney, or respiratory disease.
- If you have Parkinson's disease.
- If you have epilepsy.
- If you have diabetes.
- If you suffer from depression.
- If there is a history of glaucoma (increased eyeball pressure) in your family.
- If you are suffering from alcohol withdrawal.
- If you are allergic to any foods, preservatives or dyes.
- If you suffer from hypothyroidism which is a condition of the thyroid gland.
- If you suffer from myasthenia gravis which is a weakness of certain muscles.
- If you suffer from phaeochromocytoma which causes an increase in blood pressure.
- If you suffer from prostatic hypertrophy which is enlargement of the prostate gland.
- If you have any blood disorders.
- If you or someone else in your family has a history of blood clots, as medicines like Terra-Zine have been associated with formation of blood clots.

Use in pregnancy and while breast-feeding.

Tell your doctor if you are pregnant or planning a pregnancy and if you are breast-feeding, as Terra-zine should not be used in pregnancy or while breast-feeding.

The following symptoms may occur in newborn babies, of mothers that have used trifluoperazine in the last trimester (last three months of their pregnancy); shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Can you drive when taking Terra-zine?

Because of the risk of impaired alertness it is advisable not to drive or operate machinery.

Can you take Terra-zine with other medicines?

It is very important to tell your doctor or pharmacist about all the medicines that you are taking, whether or not any medicines were prescribed by your doctor or bought without a prescription from the pharmacy or elsewhere. Your doctor will be able to identify medicines you should not take with Terra-zine.

If you are taking other medicines. Some medicines will affect the actions of Terra-zine e.g. central nervous system depressant drugs such as alcohol, sedatives, barbiturates, sleeping pills. Other medicines which interfere with the actions of Terra-zine, or which are interfered with by the use of Terra-zine include:

- Guanethidine and clonidine (for high blood pressure).
- Anti-Parkinsonian drugs such as levodopa and benzhexol, and other anticholinergic drugs (e.g. orphenadrine, benztropine).
- Anti-diabetic drugs (meformin, chlorpropamide).
- Anticoagulant drugs (blood thinning medicines such as

warfarin)

- Medicines used to treat heart conditions and high blood pressure (e.g. quinidine, corticosteroids, digoxin, diazoxide).
- Lithium, used for psychological disorders.
- Sympathomimetic agents, which increase heart rate and contraction of heart muscle.
- Anti-depressants, which are used to treat depression.
- Antacids, used to treat increased stomach acidity.

Tea and coffee can affect the absorption of Terra-zine. Antacids will also affect the absorption of Terra-zine.

If you go to a doctor, dentist or hospital for any reason, tell them you are taking Terra-zine.

When and how to take Terra-zine.

This medicine is to be taken by mouth and only in the doses prescribed by your doctor. Do not take more and do not take more often.

You will be prescribed the lowest dose necessary to control your symptoms. Do not stop taking your medicine or change the dose unless your doctor tells you to, and for the shortest possible time excepting under certain conditions where your doctor believes that long-term treatment is required.

Do not stop taking your medicine or change the dose unless your doctor tells you to.

Usual dosages are stated below:

ADULTS:

The recommended dosage when Terra-zine is used together with other medicines for the short-term management of anxiety, agitation, excitement, and impulsive behaviour is: - 2-4 mg a day in divided doses. This dosage may be increased to a maximum of 6 mg per day in divided doses.

When Terra-zine is used together with other medicines for the short-term management of anxiety or severe agitation, and excitement, violent or dangerous impulsive behaviour the recommended dose is 2-4mg a day in divided doses, which may be increased to a maximum of 6mg per day in divided doses.

In the treatment of the symptoms of schizophrenia, and psychological disorders, the recommended starting dose is 5 mg twice a day for physically fit adults. This dose may be increased after one week if necessary to 15 mg a day. Further increases may be made of 5 mg at 3 day intervals; this is the minimum time that should be allowed to elapse between dosage increases.

After satisfactory control has been achieved the dosage may be gradually reduced until an affective dosage maintenance level is arrived at.

After commencing treatment it may take several weeks for improvement to be felt. It is always necessary that withdrawal from treatment should be gradual to avoid a relapse of the condition if stopping treatment is sudden.

ELDERLY:

A quarter or half the normal starting dose may be sufficient for therapeutic response in the elderly.

CHILDREN:

Not recommended for use in children.

GENERAL:

Terra-zine should always be used for the minimum possible time at the minimal effective dosage level excepting where it is established that long-term administration for conditions such as schizophrenia is required.

What to do if too many tablets are taken at the same time.

If you accidentally take more tablets than recommended contact your nearest doctor or hospital casualty department at once. Take any remaining tablets with you and keep in the original container or packaging so that they can be identified.

What if you miss a dose?

If you miss a dose, skip the missed dose and go back to your regular dosage schedule. Do not take two doses at once. If you feel that this medicine is not working as well after you have taken it for a short time (3-4 days) do not increase the dose, instead check with your doctor.

What side effects can Terra-zine have?

Common side effects noticed particularly at the start of treatment and with high dosages include drowsiness, sedation, dry mouth and nasal stuffiness.

Terra-zine may affect concentration and alertness, particularly at the start of treatment. These effects will be increased by the consumption of alcohol.

In very hot weather or very cold weather, and particularly with the elderly, there is a risk of heat stroke or hypothermia. The elderly also have increased risk of low blood pressure which can be caused by moderate to high doses of trifluoperazine.

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Other dose-related side effects include blurring of vision, alterations of heart beat, constipation and difficulty passing urine.

Some reactions are common and can occur at low dosages, though are more common at moderate to high dosage. These include muscle rigidity (stiffness), tremor (fine shaking of the hands), jerky body movements and the inability to control movements of the hand and body. There is a risk of sustained fixed movement of the eyes and head (oculogyric crises) though this is more common in Parkinson patients. Anti-Parkinson medicines (such as levodopa) used together with trifluoperazine may aggravate these conditions and therefore should be avoided. These side effects may present themselves immediately or shortly after you stop taking this medicine. Abrupt drug withdrawal can increase the risk of these side effects.

Random repetitive unintentional movements (known as tardive dyskinesia) is a symptom which can occur when taking Terra-zine. It is characterised by grimacing, lip smacking, and sticking your tongue out without wishing to. It is more common in the elderly, but is also common among

patients taking high doses of Terra-zine over a long time. Taking Anti-Parkinson medicines with Terra-zine can also cause it.

A combination of high temperature, pale complexion, muscle stiffness and changes in levels of alertness are symptoms of a serious condition called 'neuroleptic malignant syndrome'. If these symptoms develop, you should inform your doctor immediately.

In low doses, Terra-zine can cause the following side effects, which will disappear on their own, or once the medicine is stopped. These side effects are: feelings of being mentally slowed down or dulled, sickness, dizziness, headache, excitement, agitation, and sleeplessness. Confusion and epileptic fits (seizures) can also occur. Stopping the medication suddenly can lead to sickness, difficulty in sleeping and vomiting.

Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty breathing.

Various types of blood disorders may occur. Be sure to tell your doctor if you are suffering from bruising or an unusually bad sore throat, or fever.

Rarely Terra-zine may cause problems with your liver. If you notice a yellowing of your skin or eyeballs tell your doctor. You may have to stop taking your medicine.

Trifluoperazine rarely causes sunburn with exposure to sunlight, and can cause skin rashes and sensitivity. With long-term use trifluoperazine can change skin pigmentation (colour). Very rarely, and only with excessively high doses, vision may become impaired due to pigment deposits in the eye. Terra-zine can also cause thickening of the skin.

The use of trifluoperazine can lead to hormonal changes: enlargement of the breasts, production of breast milk, reduction or stopping of monthly periods. The use of Terra-zine can also affect sexual function. Weight gain is common. Water retention and increased levels in the blood of cholesterol and sugar have been reported as side effects of trifluoperazine.

After withdrawal of Terra-zine the following may occur: writhing movements, smacking of the lips, protrusion of the tongue, chewing movements and facial grimaces. Repetitive movements of the neck or trunk may occur. These withdrawal symptoms are not likely to occur with low doses used as recommended. Because withdrawal symptoms may be related to length of treatment as well as daily dose, Terra-zine should always be given in the smallest effective dose for the shortest possible time.

If you notice any of the above reactions or side effects, or if you notice other unusual or worrying changes contact your doctor.

Storing your medicine

You must keep this medicine in a safe place where children cannot get at it. Your medicine could harm them.

Keep your medicine in a dry place, below 25°C. Protect from light. Keep the tablets in the container in which they were given to you.

If your doctor tells you to stop the treatment, return any remaining tablets/capsules to the pharmacist.

On the container, you will find the words "expiry date" followed by numbers indicating the day, month and year. This is the date after which the medicine is no longer fit for use. Do not use the medicine after this date but return it to your doctor or pharmacist.

A reminder

REMEMBER this medicine is for you. Never give it to someone else, even if their symptoms are the same as yours.

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

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