

TETRABENAZINE TABLETS

Tetrabenazine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tetrabenazine Tablets. It does not contain all the available information. Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking Tetrabenazine Tablets against the benefits they expect it will have for you.

If you have any concerns about taking Tetrabenazine Tablets, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tetrabenazine Tablets are used for

Tetrabenazine is used for the treatment of diseases, which cause jerky, irregular, uncontrollable movements such as Huntington's chorea, senile chorea and hemiballismus.

Tetrabenazine affects some chemicals in the brain, and by doing so it helps to control jerky and irregular movements.

Ask your doctor if you have any questions about why Tetrabenazine Tablets have been prescribed for you.

Your doctor may have prescribed Tetrabenazine Tablets for another use.

Tetrabenazine Tablets are not addictive.

Tetrabenazine Tablets are only available on a doctor's prescription.

Before you take Tetrabenazine Tablets

When you must not take it

Do not take Tetrabenazine Tablets if you have an allergy to:

- Any medicine containing tetrabenazine.
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin.

Do not take Tetrabenazine Tablets if you are also taking:

- Medicine containing reserpine.
- Medicine containing levodopa
- Medicine known as a monoamine oxidase inhibitor or have taken this medicine in the past 2 weeks.

Tetrabenazine can affect action of these medicines.

Do not take Tetrabenazine Tablets if you have:

- Parkinson's disease.
- Depression.
- Galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

Tetrabenazine Tablets contain lactose.

Do not take Tetrabenazine tablets if you are pregnant or breastfeeding.

Tetrabenazine may harm your unborn baby. Tetrabenazine has been found in breast milk.

Do not take Tetrabenazine Tablets after the expiry date printed on the bottle.

Do not take Tetrabenazine Tablets if the bottle seems to have been opened or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have or have had any of the following medical conditions:

- Allergy to any other medicines, foods, preservatives or dyes
- Lactose intolerance. Tetrabenazine Tablets contain lactose.
- Depression
- Suicidal thoughts or behaviour
- Parkinson's disease
- Abnormal heart rate or rhythm
- Kidney disease
- Liver disease.

Tell your doctor your CYP2D6 metaboliser status, if known.

Your CYP2D6 metaboliser status may affect the dose of tetrabenazine you need and the dose of other medicines you may be taking.

Tell your doctor if you are pregnant or intend to become pregnant or to breastfeed.

If you have not told your doctor about any of the above, tell him/her before you start taking Tetrabenazine Tablets.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Tetrabenazine Tablets may interfere with each other. These include:

- Reserpine and levodopa
- Medicines used to treat depression, such as monoamine oxidase inhibitors (MAOIs) and CYP2D6 inhibitors, such as fluoxetine, paroxetine, quinidine, duloxetine, terbinafine, amiodarone, or sertraline
- Medicines that affect the brain and nervous system including medication used to treat psychiatric conditions, strong painkillers and medication used to help sleep
- Medicines used to treat psychosis, such as haloperidol, chlorpromazine and metoclopramide
- Medicines, including beta-blockers used to treat high blood pressure.

Some medicines, when used in combination with Tetrabenazine, may interfere with the rate and rhythm of heart beats. These include medications used to treat psychiatric conditions, antibiotics and medications used to treat problems with heart rhythm conditions.

How to take Tetrabenazine Tablets

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide the best dose for you.

The usual starting dose in adults is one tablet twice a day. This may increase to a total of 200 mg (8 tablets) a day.

The doctor will decide the best dose for children and elderly patients.

Do not take more than the dose your doctor has recommended.

If you feel unwell during your course of treatment, tell your doctor.

How to take it

Swallow the tablet or tablets with water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take Tetrabenazine Tablets

If you forget to take a dose of Tetrabenazine Tablets, skip that dose completely. Take your next dose at the normal time it is due.

Do not take a double dose to make up for the dose that you missed.

This may increase your chance of getting an unwanted side effect.

If you have trouble remembering when to take Tetrabenazine Tablets, ask your pharmacist for some hints.

If you take too many Tetrabenazine Tablets

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too many Tetrabenazine Tablets. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include nausea, vomiting, diarrhoea, confusion, hallucinations, sedation, drowsiness, sweating, low blood pressure and abnormally low body temperature.

While you are taking Tetrabenazine Tablets

Things you must do

Make sure that all of your doctors and pharmacists know you are taking Tetrabenazine Tablets. Remind them if any new medicines are about to be started.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not use Tetrabenazine Tablets to treat any complaint other than that directed by your doctor.

It may not be safe to use Tetrabenazine Tablets for another complaint.

Tetrabenazine Tablets should only be used by the person for whom it was prescribed. Do not give Tetrabenazine Tablets to anyone else even if they have the same condition as you.

It may not be safe for another person to use Tetrabenazine Tablets.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Tetrabenazine Tablets affects you.

This medicine may cause drowsiness in some people.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or get worse, talk to your doctor.

Avoid or limit the use of alcohol when taking tetrabenazine Tablets.

Alcohol can increase some side effects of tetrabenazine such as dizziness, drowsiness and difficulty in concentrating.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tetrabenazine Tablets.

Like all medicines, Tetrabenazine Tablets may have some side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following:

- Sleepiness and drowsiness
- Depression
- Uncontrollable movements of the hands, arms, legs and head (similar to those in Parkinson's disease)
- Digestive problems
- Lowering of blood pressure
- Feeling nervous or anxious

- Worsening aggression
- Trouble sleeping
- Skin rash.

Tell your doctor immediately if you notice any of the following:

- Difficulty in swallowing
- Choking attacks
- Stiffness or tightness in the arms or legs
- Confusion or having thoughts of irrational ideas not shared by others
- Suicidal thoughts or behaviour.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

After taking Tetrabenazine Tablets

Storage

Keep Tetrabenazine Tablets in their bottle until it is time to take your dose.

If you take them out of their container, they may not keep well.

Keep Tetrabenazine Tablets in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot or cold days.

Heat and dampness can destroy some medicines.

Keep Tetrabenazine Tablets where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Tetrabenazine Tablets look like

Tetrabenazine Tablets 25 mg are buff coloured. They are scored and marked with "CL" over "25".

Ingredients

Each Tetrabenazine Tablet contains 25 mg of the active ingredient, tetrabenazine, and 64 mg lactose.

Tetrabenazine Tablets also contain the following inactive ingredients:

- Starch
- Talc
- Magnesium stearate
- Iron oxide yellow.

Tetrabenazine Tablets are available in plastic bottles containing 112 tablets.

Supplier

Tetrabenazine Tablets are distributed in Australia by:

iNova Pharmaceuticals (Australia) Pty Limited
ABN: 13 617 871 539
Level 10, 12 Help Street
Chatswood NSW 2067
Tel: 1800 630 056
AUST R 13695

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