

# Tetrabenazine Tablets

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking Tetrabenazine?

Tetrabenazine tablets contains the active ingredient tetrabenazine. Tetrabenazine is used to treat diseases which cause jerky, irregular, uncontrollable movements such as Huntington's chorea, senile chorea and hemiballismus.

For more information, see Section [1. Why am I taking Tetrabenazine?](#) in the full CMI.

### 2. What should I know before I take Tetrabenazine?

Do not take if you have ever had an allergic reaction to Tetrabenazine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take Tetrabenazine?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Tetrabenazine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I take Tetrabenazine?**

- Adults: The usual starting dose is one tablet twice a day. This may be increased to up to 8 tablets a day.
- Children: The usual starting dose is 1/2 tablet twice a day with increases of 1/2 tablet per day every 3 to 4 days until the desired effect is achieved.

More instructions can be found in Section [4. How do I take Tetrabenazine?](#) in the full CMI.

### **5. What should I know while taking Tetrabenazine?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist</li></ul>
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	<p>you visit that you are taking Tetrabenazine.</p> <ul style="list-style-type: none"> <li>● If you are having surgery, tell the surgeon or anaesthetist that you are taking Tetrabenazine.</li> <li>● Tell your doctor immediately if you become pregnant while using this medicine.</li> <li>● Get up slowly when standing up or getting out of bed as Tetrabenazine may cause light-headedness, dizziness, or faintness.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop taking this medicine suddenly or change the dose without checking with your doctor.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful driving or operating machinery until you know how Tetrabenazine affects you.</li> <li>● Tetrabenazine may cause drowsiness in some people.</li> </ul>

<p><b>Drinking alcohol</b></p>	<ul style="list-style-type: none"> <li>● Avoid drinking alcohol while taking Tetrabenazine.</li> <li>● Alcohol can increase some side effects such as dizziness, drowsiness, and difficulty concentrating.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Store tablets below 30°C in a cool dry place.</li> <li>● Keep out of reach of children.</li> </ul>

For more information, see Section [5. What should I know while taking Tetrabenazine?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects include drowsiness, Parkinsonism symptoms such as tremor, balancing problems and excessive salivation, depression, agitation, anxiety, insomnia, confusion, difficulty swallowing or choking attacks. Serious side effects include stiffness or tightness in the arms or legs, irrational thoughts or ideas, or suicidal thoughts or behaviour.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Tetrabenazine Tablets

Active ingredient: *Tetrabenazine*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Tetrabenazine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tetrabenazine.**

**Where to find information in this leaflet:**

- [1. Why am I taking Tetrabenazine?](#)
- [2. What should I know before I take Tetrabenazine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Tetrabenazine?](#)
- [5. What should I know while taking Tetrabenazine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking Tetrabenazine?

**Tetrabenazine tablets contain the active ingredient tetrabenazine.** Tetrabenazine works in the central nervous system to prevent the absorption of certain chemicals, such as dopamine and serotonin, which helps to control jerky and irregular movement.

**Tetrabenazine is used to treat diseases which cause jerky, irregular or uncontrollable movements such as Huntington's chorea, senile chorea and hemiballismus.**

## **2. What should I know before I take Tetrabenazine?**

### **Warnings**

#### **Do not take Tetrabenazine if:**

- you are allergic to tetrabenazine, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction 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.
- Always check the ingredients to make sure you can use this medicine.
- you are taking reserpine or levodopa
- you are taking a medicine known as a monoamine oxidase inhibitor (MAOI) or you have taken this medicine in the past 2 weeks
- you have Parkinson's disease. Tetrabenazine can make pre-existing Parkinsonism worse.

- you suffer from depression. Tetrabenazine may cause depression, worsen pre-existing depression, or result in suicidal ideation and behaviour.
- you have a galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. Tetrabenazine tablets contain lactose.

### **Check with your doctor if you:**

- Have any other medical conditions including:
  - abnormal heart rate or rhythm
  - kidney or liver disease
  - high or low blood pressure
  - lactose intolerance or malabsorption
  - suicidal thoughts or behaviour
  - take any medicines for any other condition.

Tell your doctor if you know your CYP2D6 metaboliser status. Your CYP2D6 metaboliser status may affect the Tetrabenazine dose you need and the dose of other medicines you may be taking.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Do not take Tetrabenazine if you are pregnant or intend to become pregnant. Tetrabenazine crosses the placenta and may harm your unborn baby.

Do not take Tetrabenazine tablets if you are breast-feeding. Tetrabenazine passes into breast milk.

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with Tetrabenazine and affect how it works. These include:**

- medicines that affect the brain and nervous system including medicines to treat psychiatric conditions, opioid painkillers and sleeping pills
- medicines for high blood pressure, including beta blockers
- medicines used to treat psychosis such as haloperidol, and chlorpromazine
- metoclopramide used control nausea and vomiting
- medicines for abnormal heart rhythms
- antibiotics.

**Medicines that may increase the effect of Tetrabenazine include:**

- medicines to treat depression called tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs) or CYP2D6 inhibitors, such as fluoxetine, paroxetine, sertraline, quinidine, duloxetine, terbinafine, and amiodarone.



**Tetrabenazine may reduce the effect of the following medicines:**

- reserpine or levodopa

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tetrabenazine.**

## **4. How do I take Tetrabenazine?**

### **How much to take**

- Your doctor will decide the best dose for you. Follow your doctor's instructions.
- The usual adult dose is one tablet twice a day. The dose may be increased up to 8 tablets a day.
- The usual children's dose is 1/2 tablet twice a day with increases of 1/2 tablet per day every 3 to 4 days until the desired effect is achieved
- Swallow tablets with a glass of water.

### **When to take Tetrabenazine**

- Take your medicine about the same time each day, once in the morning and once in the evening.

### **If you forget to take Tetrabenazine**

Tetrabenazine should be taken regularly at the same time each day.

**If you miss a dose and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

This may increase your risk of having an unwanted side effect.

## **If you take too much Tetrabenazine**

If you think that you have taken too much Tetrabenazine, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking Tetrabenazine?**

### **Things you should do**

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 out of bed or from chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

### **Call your doctor straight away if you:**

- experience symptoms of Parkinsonism, which include unsteadiness, tremors, and excessive salivation. Your doctor may need to adjust your dose of Tetrabenazine.
- become pregnant while taking Tetrabenazine.

Remind any doctor, dentist or pharmacist you visit that you are taking Tetrabenazine.

If you are having surgery, tell the surgeon or anaesthetist that you are taking Tetrabenazine. It may affect other medicines used during surgery.

### **Things you should not do**

- Do not stop taking Tetrabenazine or change the dose without checking with your doctor.
- Do not use Tetrabenazine tablets to treat any condition other than that directed by your doctor.
- Do not give Tetrabenazine to anyone else even if they have the same condition as you. It may not be safe for another person to take Tetrabenazine.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Tetrabenazine affects you.**

Tetrabenazine may cause drowsiness in some people.

## **Drinking alcohol**

### **Tell your doctor if you drink alcohol.**

Drinking alcohol while taking Tetrabenazine is not recommended. Alcohol can increase some side effects of Tetrabenazine such as dizziness, drowsiness and difficulty concentrating.

## **Looking after your medicine**

Follow the instructions on the bottle label on how to take care of your medicine.

Store below 30 °C in the bottle until it is time to take it. Store Tetrabenazine in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Nervous system</b></p> <ul style="list-style-type: none"><li>• Sleepiness or drowsiness</li><li>• Difficulty sleeping</li><li>• Memory loss</li><li>• Changes in muscle tone</li></ul> <p><b>Psychiatric</b></p> <ul style="list-style-type: none"><li>• Restlessness</li><li>• Nervousness or anxiety</li><li>• Depression</li><li>• Worsening aggression</li><li>• Confusion</li></ul> <p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"><li>• Nausea or vomiting</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Diarrhoea or constipation</li> <li>• Stomach pain</li> <li>• Changes in appetite</li> <li>• Dry mouth</li> <li>• Excessive salivation</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>• Sweating</li> <li>• Skin rash</li> </ul> <p><b>Eye disorders</b></p> <ul style="list-style-type: none"> <li>• Light sensitivity</li> <li>• Spasmodic movement of the eyeballs into an upward fixed position</li> </ul> <p><b>Cardiovascular</b></p> <ul style="list-style-type: none"> <li>• Slow heart rate</li> <li>• Feeling faint or dizziness</li> <li>• Blood pressure changes</li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>• Fatigue, weakness, or exhaustion</li> <li>• Lactation</li> <li>• Irregular menstrual cycle</li> </ul>	

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• Difficulty swallowing</li><li>• Choking attacks</li><li>• Muscle rigidity accompanied by mental changes, sweating, very high fever and fluctuations in blood pressure</li><li>• Confusion or having thoughts of irrational ideas not shared by others</li><li>• Suicidal thoughts or behaviour</li><li>• Uncontrollable movements of the hands, arms, legs, or head (similar to those seen with Parkinson's disease), which may be accompanied by unsteadiness and excessive salivation.</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Tetrabenazine contains

<b>Active ingredient (main ingredient)</b>	Tetrabenazine
<b>Other ingredients (inactive ingredients)</b>	Starch Talc Lactose Magnesium stearate



	Iron oxide yellow
<b>Potential allergens</b>	Lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Tetrabenazine looks like**

Tetrabenazine tablets are yellowish coloured and contain 25 mg tetrabenazine as the active ingredient. They are scored and marked with "CL" over "25". They are supplied in bottles containing 112 tablets.

Registration number AUST R 13695

## **Who distributes Tetrabenazine**

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539

Level 10, 12 Help Street

Chatswood NSW 2067

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