### **TETRABENAZINE SUN**

#### **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.

#### 1. Why am I using TETRABENAZINE SUN?

TETRABENAZINE SUN contains the active ingredient Tetrabenazine. TETRABENAZINE SUN is used for the treatment of 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 using TETRABENAZINE SUN? in the full CMI.

#### 2. What should I know before I use this medicine?

Do not use 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 plan to become pregnant.

Do not take TETRABENAZINE SUN if you are pregnant or breastfeeding.

For more information, see Section 2. What should I know before I use this medicine? in the full CMI.

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

Some medicines may interfere with TETRABENAZINE SUN 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 use this medicine?

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. More instructions can be found in Section 4. How do I use this medicine? in the full CMI.

### 5. What should I know while using this medicine?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using this medicine.	
Things you should not do	Do not take TETRABENAZINE SUN if you are also taking medicines containing reserpine, levodopa or monoamine oxidase inhibitor. Do not take TETRABENAZINE SUN if you have: Parkinson's disease, Depression, Galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. TETRABENAZINE SUN tablets contain lactose.	
Driving or using machines	This medicine may cause light-headedness, dizziness, faintness, drowsiness in some people when getting out of bed or standing up, get up slowly.	
Drinking alcohol	Alcohol can increase some side effects of tetrabenazine such as dizziness, drowsiness and difficulty in concentrating.	
Looking after your medicine	<ul> <li>Keep TETRABENAZINE SUN in their bottle until it is time to take your dose.</li> <li>Keep TETRABENAZINE SUN in a cool dry place where the temperature stays below 25°C.</li> </ul>	

For more information, see Section 5. What should I know while using this medicine? in the full CMI.

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

If you experience sleepiness, drowsiness, depression, ucontrollable 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, aggravated or trouble sleeping, or skin rash issues, speak to your doctor. 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 SUN

Active ingredient(s): Tetrabenazine

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using TETRABENAZINE SUN. 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 this medicine.

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

- 1. Why am I using TETRABENAZINE SUN?
- 2. What should I know before I use this medicine?
- 3. What if I am taking other medicines?
- 4. How do I use this medicine?
- <u>5.</u> What should I know while using this medicine?
- 6. Are there any side effects?
- 7. Product details

#### 1. Why am I using TETRABENAZINE SUN?

TETRABENAZINE SUN contains the active ingredient tetrabenazine.

TETRABENAZINE SUN 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 SUN have been prescribed for you. Your doctor may have prescribed TETRABENAZINE SUN for another use TETRABENAZINE SUN are not addictive.

# 2. What should I know before I use this medicine?

#### Warnings

#### Do not use this medicine if:

- you are allergic to tetrabenazine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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 SUN 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 SUN if you have:** 

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

TETRABENAZINE SUN contain lactose.

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

Allergy to any other medicines, foods, preservatives or dyes

- Lactose intolerance. TETRABENAZINE SUN 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.

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

## Do not take TETRABENAZINE SUN if you are pregnant or breastfeeding.

Tetrabenazine may harm your unborn baby. Tetrabenazine has been found in 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:

- 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.

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 SUN.

#### 4. How do I use this medicine?

#### 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.

#### When to take this medicine

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 to take this medicine

Swallow the tablet or tablets with water.

#### If you forget to use this medicine

If you forget to take a dose of TETRABENAZINE SUN, 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 SUN, ask your pharmacist for some hints.

#### If you use too much of this medicine

If you think that you have used too much TETRABENAZINE SUN, 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 using this medicine?

#### Things you should do

Make sure that all of your doctors and pharmacists know you are taking TETRABENAZINE SUN. 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.

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

- 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.

Remind any doctor, dentist or pharmacist you visit that you are using TETRABENAZINE SUN.

#### Things you should not do

Do not use TETRABENAZINE SUN to treat any complaint other than that directed by your doctor. It may not be safe to use TETRABENAZINE SUN for another complaint.

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

It may not be safe for another person to use TETRABENAZINE SUN.

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

#### **Driving or using machines**

Be careful driving or operating machinery until you know how TETRABENAZINE SUN 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. Be careful before you drive or use any machines or tools until you know how this medicine affects you.

#### **Drinking alcohol**

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

Avoid or limit the use of alcohol when taking TETRABENAZINE SUN. Alcohol can increase some side effects of tetrabenazine such as dizziness, drowsiness and difficulty in concentrating.

#### Looking after your medicine

## Keep TETRABENAZINE SUN in their bottle until it is time to take your dose.

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

You should not take any left over tablets 28 days (4 weeks) after opening the bottle. Take these tablets to your local pharmacy for safe disposal.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, where the temperature stays below 25°C; for example, do not store it:

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

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
<ul> <li>Sleepiness and drowsiness</li> <li>Depression</li> <li>Uncontrollable movements of the hands, arms, legs and head (similar to those in Parkinson's disease)</li> <li>Digestive problems</li> <li>Lowering of blood pressure</li> <li>Feeling nervous or anxious</li> <li>Worsening aggression</li> <li>Trouble sleeping</li> <li>Skin rash</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

#### Serious side effects

Serious side effects	What to do
<ul> <li>Difficulty in swallowing</li> <li>Choking attacks</li> <li>Stiffness or tightness in the arms or legs</li> <li>Confusion or having thoughts of irrational ideas not shared by others</li> <li>Suicidal thoughts or behaviour.</li> </ul>	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.

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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 SUN contains

Active ingredient (main ingredient)	Tetrabenazine	
Other ingredients (inactive ingredients)	<ul> <li>Maize Starch</li> <li>Lactose</li> <li>Purified Talc</li> <li>Sodium starch Glycollate type A</li> <li>Colloidal anhydrous silica</li> <li>Magnesium stearate</li> <li>Iron oxide yellow.</li> </ul>	
Potential allergens	Lactose	

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

#### What this medicine looks like

TETRABENAZINE SUN Tablets 25 mg are yellow, circular, flat faced beveled edge uncoated tablet debossed with "179" on one side and scored on the other side. AUST R 381235

#### Who distributes this medicine

TETRABENAZINE SUN Tablets are distributed in Australia

by:

Sun Pharma ANZ Pty Ltd

Macquarie Park Sydney NSW 2113

customer service. aus@sunpharma.com

Tel: 1800 726 229

This leaflet was prepared in November 2022.