

# Tensodeine®

Paracetamol, codeine phosphate, doxylamine succinate

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Tensodeine.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

### What Tensodeine is used for

Tensodeine is a type of analgesic used to relieve pain and tension.

It is used for the relief of moderate to severe pain including toothache or pain from injury or surgery, and for the temporary relief of headache. In addition, the calmative properties of Tensodeine may be especially useful in the treatment of tension headache, migraine and period pain.

Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Doxylamine is an antihistamine with calmative effects.

Your doctor, however, may prescribe Tensodeine for another purpose.

**Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.**

This medicine may be habit-forming if taken frequently or over long periods.

### Before you take it

*When you must not take it*

**Do not take Tensodeine if you have:**

- An allergic reaction to paracetamol, codeine or doxylamine
- Respiratory depression
- G6PD deficiency, a human enzyme deficiency

**Do not take Tensodeine if you are allergic to it or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

**Tensodeine is not recommended for use in children under 12 years of age.**

**Do not take Tensodeine during the third trimester of pregnancy.**

**Do not take Tensodeine during labour, especially if the baby is premature.**

This may produce withdrawal effects in the newborn baby.

**Do not take it if you are breast-feeding or planning to breast-feed.**

Tensodeine passes into breast milk and there is a possibility your baby may be affected.

**Do not take it after the expiry date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

**Do not take it if the packaging is torn/damaged or shows signs of tampering.**

*Before you start to take it*

**Tell your doctor or pharmacist if you have allergies to:**

- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes
- aspirin or any other NSAID medicine.

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

Like most medicines of this kind, Tensodeine is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- liver problems
- kidney problems
- asthma

**Tell your doctor or pharmacist if you plan to have surgery.**

**If you have not told your doctor or pharmacist about any of the above, tell them before you take Tensodeine.**

### *Taking other medicines*

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

Some medicines may interfere with the absorption of Tensodeine.

These include:

- Antihistamines
- Sleeping tablets
- Tranquillisers (medicines used for anxiety or nerves)
- Any medicine which thins the blood
- Medicine to treat epilepsy
- Metoclopramide, a medicine used to control nausea and vomiting
- Propantheline, a medicine used to treat stomach ulcers
- Chloramphenicol
- Zidovudine and rifampicin, medicines used to treat infections
- Antidepressants

These medicines may be affected by Tensodeine, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Tensodeine.

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## How to take it

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### *How much to take*

The standard dose of this medicine for adults and children 12 years or over is one or two caplets every 4 to 6 hours, as needed for pain relief.

Do not take more than 8 caplets in a 24 hour period.

Your doctor may have prescribed a different dose.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how many to take.

**Follow the instructions they give you.**

If you take the wrong dose, Tensodeine may not work as well and your problem may not improve.

**Tensodeine is not recommended for use in children under 12 years of age.**

### *How to take it*

**Swallow the tablets whole with a full glass of water or other liquid.**

### *When to take it*

Tensodeine can be taken with or without food.

**If you are not sure when to take it, ask your doctor or pharmacist.**

### *If you forget to take it*

**Do not try to make up for missed doses by taking more than one dose at a time.**

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

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

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

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering when to take your medicine, ask your pharmacist for hints.**

### *If you take too much (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Tensodeine.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention. Large amounts of paracetamol can cause liver damage.

If children take too many Tensodeine they can suffer from nightmares, hallucinations, fitting or have difficulty sleeping.

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## While you are taking it

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### *Things you must do*

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Tensodeine.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Tensodeine.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.**

**If you become pregnant while you are taking this medicine, tell your doctor or pharmacist that you are taking Tensodeine.**

### *Things you must not do*

**Do not take more than the recommended dose unless your doctor or pharmacist tells you to.**

**Do not give this medicine to anyone else, even if they have the same condition as you.**

**Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.**

## Things to be careful of

**Tensodeine may cause dizziness or light-headedness in some people, especially after the first dose.**

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Children should not ride bicycles if affected and should be supervised to avoid potential harm.

**Be careful if you are over 65 and unwell or taking other medicines.**

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

**Drinking alcohol increases the likelihood of becoming drowsy while taking Tensodeine. Drinking alcohol and taking paracetamol at the same time can cause liver damage. It is not recommended that you drink alcohol while taking Tensodeine.**

**Tensodeine may be habit forming if taken at high doses for extended periods of time.**

Ask your doctor or pharmacist if you are concerned about this.

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## Side effects

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All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- Drowsiness

- Dizziness
- Nausea
- Vomiting
- Stomach pain
- Constipation
- Skin rashes
- Sweating
- Difficulty breathing
- Diarrhea
- Dry mouth

**Tell your doctor as soon as possible if you notice any of the following:**

- Painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills
- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)

**If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- hives
- fainting
- yellowing of the skin and eyes (jaundice).

**These are very serious side effects. If you have them, you may have had a serious allergic reaction to Tensodeine. You may need urgent medical attention or hospitalisation.**

These side effects are very rare.

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

Other side effects not listed above may occur in some consumers.

**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.**

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## After taking it

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**If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.**

### Storage

**Keep your caplets in the blister pack until it is time to take them.**

If you take the caplets out of the box or the blister pack they may not keep well.

**Keep the medicine in a cool, dry place where the temperature stays below 30°C.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep it 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 or pharmacist tells you to stop taking Tensodeine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### What it looks like

Tensodeine is available as caplets. The caplets are yellow, capsule shaped tablets, single scored and blank on both sides.

The caplets are available in a box containing 20 caplets.

### *Ingredients*

#### **Active Ingredient:**

Each Tensodeine caplet contains:

- Paracetamol 450 mg
- Codeine phosphate 9.75 mg
- Doxylamine succinate 5 mg

#### **Inactive Ingredients:**

Each Tensodeine caplet contains:

- cellulose
- purified talc
- magnesium stearate
- sodium starch glycollate
- colouring agents - quinoline yellow and sunset yellow

Tensodeine does not contain aspirin, gluten, sucrose, lactose, tartrazine or any other azo dyes.

### *Manufacturer/Sponsor*

Tensodeine is supplied in Australia by:

#### **Sandoz Pty Ltd**

ABN 60 075 449 553

19 Harris Street

Pymont NSW 2009

Australia

Tel: 1800 634 500

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