

Temgesic Sublingual Tablets

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Temgesic sublingual tablets?

Temgesic sublingual tablets contains the active ingredient buprenorphine (as hydrochloride). Temgesic sublingual tablets is used for the short term relief of severe pain.

For more information, see Section [1. Why am I using Temgesic sublingual tablets?](#) in the full CMI.

2. What should I know before I use Temgesic sublingual tablets?

Do not use if you have ever had an allergic reaction to Temgesic sublingual tablets 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 use Temgesic sublingual tablets?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Temgesic sublingual tablets 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 Temgesic sublingual tablets?

- Usual recommended dose for Temgesic sublingual tablets is 1 to 2 tablets dissolved under the tongue every 6 to 8 hours.
- Temgesic sublingual tablets must be placed under the tongue (sublingually) for about 10 minutes.

More instructions can be found in Section [4. How do I use Temgesic sublingual tablets?](#) in the full CMI.

5. What should I know while using Temgesic sublingual tablets?

Things you should do	<ul style="list-style-type: none">• Keep the tablet under the tongue for about 10 minutes until fully dissolved• Remind any doctor, dentist or pharmacist you visit that you are using Temgesic sublingual tablets.• For athletes, tell your doctor that you are using Temgesic sublingual tablets, as it may cause a positive reaction to "anti-doping" tests.
Things you should not do	<ul style="list-style-type: none">• Do not chew or swallow the tablet (the tablet will not work).• Do not stop using this medicine suddenly.• Do not take Temgesic to treat any condition other than the one prescribed for by your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Temgesic sublingual tablets affects you.
Drinking alcohol	<ul style="list-style-type: none">• Temgesic sublingual tablets can cause drowsiness, which may be made worse if you also drink alcohol or take certain other medicines.
Looking after your medicine	<ul style="list-style-type: none">• Keep Temgesic sublingual tablets in its original pack until it is time to use it.• Keep it in a cool, dark and dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Temgesic sublingual tablets?](#) in the full CMI.

6. Are there any side effects?

Common side effects include drowsiness, sleep from which you can be easily awoken, vertigo, dizziness and nausea. Serious side effects may include life threatening allergic reactions, difficulty breathing, swelling, and anaphylactic shock. 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.

WARNING:**Limitations of use**

Temgesic tablets should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Temgesic tablets poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Temgesic tablets can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Temgesic tablets and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using Temgesic tablets

Using Temgesic tablets with other medicines that make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Temgesic tablets.

Temgesic Sublingual Tablets

Active ingredient(s): *Buprenorphine (as hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Temgesic sublingual tablets. **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 Temgesic sublingual tablets.**

Where to find information in this leaflet:

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

1. Why am I using Temgesic sublingual tablets?

Temgesic sublingual tablets contains the active ingredient buprenorphine (as hydrochloride). Temgesic belongs to a group of medicines called opioid (narcotic) analgesics.

Opioid analgesics act directly on the brain and spinal cord to block the sensation of pain.

Temgesic is a “pain killer”. It is used for the short term relief of severe pain.

2. What should I know before I use Temgesic sublingual tablets?

Warnings

Do not use Temgesic sublingual tablets if:

- you are allergic to buprenorphine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- allergic to opioid (narcotic) medicines.
- pregnant.
- breast-feeding.
- a child.
- suffering from severe or acute respiratory disease.

Check with your doctor if you:

- you have been given Temgesic sublingual tablets (buprenorphine) before and had any problems with it.
- have any allergies to
 - any ingredients in this medicine (see Product Description at the end of this leaflet).
 - Other strong analgesics (pain killers) e.g. Morphine
 - Any other substances such as foods, preservatives or dyes
- have any of these medical conditions:

- asthma or other breathing problems
 - thyroid problems
 - prostate problems
 - problems with excess alcohol use
 - Addison's disease
 - Kyphoscoliosis (hunchback disease)
 - Low blood pressure problems
 - liver problems
 - kidney problems
 - if you are pregnant
 - biliary tract problems
 - head injuries or a condition where you have increased pressure within your head
 - stomach (abdominal) pains
 - severe mental problems or hallucinations (seeing or hearing things that are not really there)
- Some people who are taking or using opioid medicines or drugs may experience opioid withdrawal effects when they are given Temgesic sublingual tablets.

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

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 Temgesic sublingual tablets and affect how it works. These include:

- other strong pain killers (e.g. morphine)
- cough medicines containing opioid-related substances
- certain medicines for treating HIV/AIDS
- certain medicines for treating fungal and bacterial infections
- certain drugs for treating high blood pressure
- certain antidepressants including monoamine oxidase inhibitors
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics)
- certain medicines for treating epilepsy (fits)
- sedatives

- sedating anti-histamines
- certain anti-anxiety/anti-psychotic medicines
- certain anti-anxiety/anti-psychotic medicines
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- certain medicines for treating nausea/vomiting, allergies or travel sickness (antihistamines or antiemetics)
- muscle relaxants
- medicines to treat Parkinson's disease
- general anaesthetics
- naltrexone
- cannabis

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Temgesic sublingual tablets

4. How do I use Temgesic sublingual tablets?

How much to take / use

- Temgesic sublingual tablets must be placed under the tongue (sublingually). The tablets should be kept under the tongue for about 10 minutes until fully dissolved.
- The tablets will not work if you chew or swallow them whole, or are split or broken before you take them.
- The usual recommended dose is 1 to 2 tablets dissolved under the tongue every 6 to 8 hours, or as required.
- Follow the instructions provided and use Temgesic sublingual tablets until your doctor tells you to stop.

When to take / use Temgesic sublingual tablets

- Temgesic sublingual tablets should be used as per directed by your doctor.

If you forget to use Temgesic sublingual tablets

Temgesic sublingual tablets should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If 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. If you are not sure, ask your doctor or pharmacist.

If you use too much Temgesic sublingual tablets

If you think that you have used too much Temgesic sublingual tablets, 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.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while using Temgesic sublingual tablets?

Things you should do

Athletes should be aware that this medicine may cause a positive reaction to "anti-doping" tests.

Things to be careful of

TEMGESIC is intended to be used short-term and should not be used for longer than 7 days.

If used long-term and/or at higher doses beyond TEMGESIC's maximum daily dose, opioid medicines such as TEMGESIC may lead to the following issues:

Like other opioids:

TEMGESIC may cause

- breathing problems while sleeping which is known as a condition called central sleep apnoea (CSA)). If you develop symptoms like loud snoring, choking or gasping during sleep, or feeling tired during the day, this may be related to the dose of opioids. If this happens, talk to your doctor who might consider lowering your opioid dose.

- digestive system issues like difficulty of swallowing, regurgitation or chest pain not related to the heart, especially when being taken long-term.- biliary problems due to increased pressure in the bile ducts connecting the liver to the intestine, leading to symptoms such as abdominal pain or even inflammation of the pancreas.

- liver and gallbladder issues by increased pressure in the ducts leading to symptoms like pain or even inflammation of the pancreas. If you have a history of gallbladder problems or pancreatitis. Your doctor will take this into consideration when prescribing this medicine.

- hormone-related issues especially when taking this medicine long-term. This Adrenal insufficiency might result in feeling very tired or weak, feeling dizzy, loss of appetite, nausea, vomiting or low blood pressure. If your doctor thinks you might have this condition, tests may be needed to even consider stopping TEMGESIC. Androgen deficiency may cause symptoms like low libido, erectile dysfunction, irregular or missed periods or infertility.

Tolerance, dependence and addiction

This medicine contains buprenorphine which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Temgesic can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Temgesic if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.
- If you notice any of the following signs whilst taking Temgesic, it could be a sign that you have become dependent or addicted:
 - You need to take the medicine for longer than advised by your doctor
 - You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

Withdrawal

Continue taking your medicine for as long your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating

TEMGESIC given to the mother during labour, or chronic use of TEMGESIC at the end of pregnancy, can cause breathing problems and signs of withdrawal in the newborn such as rigidity, agitation, shaking convulsion or slow heart

Call your doctor straight away if you:

- notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely.

Remind any doctor, dentist or pharmacist you visit that you are using Temgesic sublingual tablets.

Things you should not do

- Do not stop using Temgesic sublingual tablets or change the dosage, without checking with your doctor.
- Do not take Temgesic sublingual tablets to treat any condition other than the one prescribed for by your doctor.
- Do not give Temgesic sublingual tablets to anyone else, even if their symptoms appear the same as yours.

Labour and newborn

Temgesic sublingual tablets given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Temgesic sublingual tablets affects you.

Temgesic sublingual tablets may cause your blood pressure to drop suddenly, causing dizziness in some people if you get up too quickly from sitting or lying down.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Temgesic sublingual tablets can cause drowsiness, which may be made worse if you also drink alcohol or take certain other medicines.

Looking after your medicine

- Keep your tablets in the original pack (blister) until it is time to take them.
- If you take the tablets out of the box or the blister pack they may not keep well.
- Keep it where the temperature stays below 30°C.
- Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them.

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, heat or sunlight; 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
<p>Common:</p> <ul style="list-style-type: none">Drowsiness or sleep from which you can be easily awokenVertigo, dizziness and nausea. <p>Less common:</p> <ul style="list-style-type: none">VomitingSweatingBlood pressure changes causing dizziness or faintingBlurred visionHeadacheDifficulty breathing or slowed breathing <p>Uncommon:</p> <ul style="list-style-type: none">Changes in heart rate or blood pressureDifficulty urinatingDry mouthWeakness/fatigueMalaiseMood changesSlurred speechTremorPaleness of skinFeeling of "pins and needles"ConfusionNervousness or uneasinessDepressionHallucinatingDreamingSkin rash/itchinessFlushing/warmthChills/cold	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • Tinnitus (ringing in the ears) • Constipation • Heartburn • Flatulence • Conjunctivitis • Coma <p>Rare:</p> <ul style="list-style-type: none"> • Loss of appetite • Diarrhoea • Hives • Convulsions (fits) • Lack of body co-ordination • Agitation <p>Unknown frequency</p> <ul style="list-style-type: none"> • Dental caries • Cases of hypersensitivity reactions have been reported. Signs and symptoms include rashes, hives, and skin itchiness. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Serious, life threatening allergic reactions have occurred, including, difficulty breathing, swelling, and anaphylactic shock. 	<p>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.</p>

OVERUSE

If TEMGESIC is used long-term and/or at higher doses beyond TEMGESIC's maximum daily dose, it may, like other opioids, lead to:

Side effects with unknown frequency include:

- dental caries
- sleep-related breathing issue
- inflammation of the pancreas
- abdominal pain
- muscle weakness
- reduced libido
- erectile dysfunction
- Difficulty swallowing
- Non cardiac chest pain

Cases of hypersensitivity reactions have been reported. Signs and symptoms include, rashes, hives, and skin itchiness. Serious, life threatening allergic reactions have occurred, including, difficulty breathing, swelling, and anaphylactic shock.

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. 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 Temgesic sublingual tablets contains

Active ingredient (main ingredient)	buprenorphine hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> ▪ lactose monohydrate ▪ mannitol ▪ maize starch ▪ povidone ▪ magnesium stearate ▪ citric acid ▪ sodium citrate dihydrate.
Potential allergens	None

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

What Temgesic sublingual tablets looks like

Temgesic sublingual tablets are available in blister packs of 20 tablets and 50 tablets.

Each blister pack of TEMGESIC Sublingual Tablets is marked with Australian Registration Number AUST R 34091.

Who distributes Temgesic sublingual tablets

Echo Therapeutics Pty Limited
 ABN 92 628 298 699
 Suite 1, 2 Kochia Lane
 Lindfield NSW 2070
 AUSTRALIA
 Medical enquiries: 1300 848 328

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