TEMGESIC Injection
Buprenorphine hydrochloride
Consumer Medicine Information

What is in this leaflet
This leaflet answers some common questions about TEMGESIC. 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 has weighed the risks of you taking TEMGESIC against the benefits they expect it will have for you.
If you have any concerns about taking TEMGESIC, ask your doctor or pharmacist.
Keep this leaflet with the medicine. You may need to read it again.

What TEMGESIC is used for
TEMGESIC is a strong "pain killer". It is used for the relief of moderate to severe pain.
TEMGESIC belongs to a group of medicines called opioid (narcotic) analgesics.
Opoid analgesics act directly on the brain and spinal cord to block the sensation of pain.
Your doctor may have prescribed TEMGESIC for another reason.
Ask your doctor if you have any questions about why TEMGESIC has been prescribed for you.
TEMGESIC contains the active ingredient, buprenorphine hydrochloride (or buprenorphine). People who take buprenorphine to relieve short term pain do not usually become addicted to it.
It is important that you discuss this issue with your doctor.

Before you are given TEMGESIC

When you must not use it
You should not be given TEMGESIC if you are:
• allergic to buprenorphine or to any of the other ingredients in this medicine (see Product Description at the end of this leaflet).
• allergic to opioid (narcotic) medicines.
• pregnant.
• breast-feeding a baby.
• a child.

You must not be given TEMGESIC if you are:
• asthma or other breathing problems
• heart problems
• liver problems
• kidney problems
• biliary tract problems
• if you have head injuries or are in a condition where you have increased pressure within your head
• stomach (abdominal) pains

It may not be safe for you to be given TEMGESIC if you have any of these conditions.

Tell your doctor if you are currently taking or have been taking other opioid medicines or drugs.
Some people who are taking or using opioid medicines or drugs may experience opioid withdrawal effects when they are given TEMGESIC.

Taking Other Medicines
Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop, before you begin treatment with TEMGESIC.
A number of medicines may change the effects of TEMGESIC. These include:
• other strong pain killers (eg morphine)
• cough medicines containing opioid-related substances
• certain medicines for treating AIDS
• certain medicines for treating fungal and bacterial infections
**While you are being given Temgesic**

**Things to be careful of**

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

**You should not drive or operate machinery until you know how TEMGESIC affects you.**

TEMGESIC can cause drowsiness, which may be made worse if you also drink alcohol or take certain other medicines. If you are drowsy, do not drive or operate machinery.

TEMGESIC may cause your blood pressure to drop suddenly, causing you to feel dizzy if you get up too quickly from sitting or lying down. If you feel light-headed or dizzy or faint, get up slowly when getting out of bed or standing up.

**Will I become addicted to TEMGESIC**

Opioid analgesics such as TEMGESIC are used to relieve moderate to severe pain. In most cases, when used as directed by your doctor, addiction does not occur. However, your body may become used to taking the TEMGESIC, so if the TEMGESIC injections are stopped suddenly you may experience some symptoms of withdrawal. It is important that you discuss this issue with your doctor.

**Side effects**

Like all drugs, TEMGESIC may cause side effects.

**Tell your doctor or nurse as soon as possible if you do not feel well after you have been given TEMGESIC.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Drowsiness, or sleep from which you can be easily awoken is common, particularly if TEMGESIC is used to relieve pain following surgery.

Less common side effects include:

- nausea
- dizziness/vertigo

Uncommon side effects include:

- dry mouth
- constipation
- headache
- weakness/fatigue
- malaise
- vomiting
- nausea/vomiting
- dizziness
- fainting
- sweating
- mood changes
- slurred speech
- tremor
- paleness of skin
- feeling of pins and needles
- confusion
- hallucinating
- dreaming
- blurred vision
- conjunctivitis
- skin reaction/irritation at injection site.
- skin rash
- skin itchiness
- flushing/warmth
- chills/cold
- tinnitus (ringing in the ears)
- changes in the way your heart beats, for example, if you notice it is beating faster or slower
- blood pressure changes
- difficulty urinating

**How TEMGESIC is given**

TEMGESIC will be given to you by injection by your doctor or specially trained nurse.

The injection may be given into a vein or into a muscle.

The usual recommended dose is 1 to 2 ampoules (300-600 micrograms of buprenorphine) repeated every 6 to 8 hours, or as required.

**Overdose**

Your doctor has information on how to recognise and treat an overdose.

Ask your doctor if you have any concerns.

- certain drugs for treating high blood pressure
- certain antidepressants including monoamine oxidase inhibitors
- certain medicines for treating epilepsy (fits)
- sedatives
- sedating anti-histamines
- certain anti-anxiety/anti-psychotic medicines
- general anaesthetics

The above medicines may be affected by TEMGESIC, or may affect how well it works.

**Do not drink alcohol or take medicines that contain alcohol while you are being treated with TEMGESIC.**

Alcohol and certain other medicines (as listed above) may increase the sedative effects of TEMGESIC, which can make driving and operating machinery hazardous.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking TEMGESIC.
- difficulty breathing or slowed breathing
- heartburn
- flatulence
- coma

Rare side effects include:
- loss of appetite
- diarrhoea
- hives
- convulsions (fits)
- lack of body co-ordination
- agitation

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 if you notice anything else that is making you feel unwell, even if it is not on the list.

Other side effects not listed above may also occur in some patients.

Each 1mL ampoule contains 324 micrograms of buprenorphine hydrochloride (equivalent to 300 micrograms of burpenorphine) as the active ingredient. The other ingredients in the ampoule are: glucose anhydrous, water for injections and hydrochloric acid for pH adjustment.

Each pack of TEMGESIC Injection is marked with Australian Registration Number: AUST R 15394

**Sponsor**
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**After using TEMGESIC**

**Storage**
If you are storing TEMGESIC Injections at home, they should be kept in the original pack in a cool dry place where the temperature stays below 30 degrees C.

TEMGESIC should be kept out of the reach of children.

**Disposal**
Return any unused medicine to your pharmacist.

**Product Description**

TEMGESIC Injection is available in packs of 5 x 1mL clear glass ampoules.