

TEMGESIC Injection

Buprenorphine (as hydrochloride)

Consumer Medicine Information

WARNINGS

Limitations of use

TEMGESIC 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 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 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 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

Using TEMGESIC 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.

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 "pain killer". It is used for the short term relief of severe pain.

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.

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 (as hydrochloride). 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 child.
- suffering from severe or acute respiratory disease

Before you are given TEMGESIC

You must tell your doctor if:

1. you have been given TEMGESIC (buprenorphine) before and had any problems with it
2. you have any allergies to
 - any ingredients in this medicine (see Product Description at the end of this leaflet).
 - other strong analgesics (pain killers) eg. morphine
 - any other substances such as foods, preservatives, or dyes.
3. you 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)

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.

You should not use benzodiazepines (medicines used to treat anxiety or sleeping problems) whilst you are taking TEMGESIC unless they are prescribed by your doctor

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 HIV/AIDS
- certain medicines for treating fungal and bacterial infections
- 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
- certain medicines for treating nerve and muscle pain, including fibromyalgia
- certain medicines for treating nausea/vomiting
- general anaesthetics
- naltrexone
- cannabis

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.

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.

If you have any questions about the dose given to you, ask your doctor.

Overdose

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

If you or someone else receive too much TEMGESIC (overdose), call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used TEMGESIC that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits.

If you think you or someone else may have used too much TEMGESIC, you should immediately:

- phone the Poisons Information Centre (in Australia telephone 13 11 26 or in New Zealand telephone 0800 POISON or 0800 764 766), 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.

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

Addiction

You can become addicted to TEMGESIC even if you take it exactly as prescribed. TEMGESIC may become habit forming causing mental and physical dependence. If

abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking TEMGESIC. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking TEMGESIC suddenly, so it important to take it exactly as directed by your doctor.

Tolerance

Tolerance to TEMGESIC may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking you 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 can cause breathing problems and signs of withdrawal in the newborn.

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 very common, particularly if TEMGESIC is used to relieve pain following surgery. Other very common side effects include dizziness, vertigo and nausea.

Less common side effects include:

- vomiting
- sweating
- blood pressure changes causing dizziness or fainting
- blurred vision
- headache
- difficulty breathing or slowed breathing

Uncommon side effects include:

- changes in heart rate or blood pressure
- difficulty urinating
- dry mouth
- weakness/fatigue
- malaise
- mood changes
- slurred speech
- tremor
- paleness of skin
- feeling of pins and needles
- confusion
- nervousness or uneasiness
- depression
- hallucinating
- dreaming
- skin reaction/irritation at injection site
- skin rash, itchiness

- flushing/warmth
- chills/cold
- tinnitus (ringing in the ears)
- constipation
- heartburn
- flatulence
- conjunctivitis
- 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.

Do not use the medicine after the expiry date.

Product Description

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

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

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

Sponsor

Echo Therapeutics Pty Ltd

Sydney, Australia

www.echotherapeutics.com.au

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After using TEMGESIC

Safe Storage

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

Keep medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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