

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S6

TEMGESIC [®] 0,2 mg Sublingual Tablets

TEMGESIC [®] 1 ml (0,3 mg/ml) Injection

Active substance: Buprenorphine (as hydrochloride)

Contains sugar:

Lactose monohydrate.

This medicine contains buprenorphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

Read all of this leaflet carefully before you start taking TEMGESIC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TEMGESIC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TEMGESIC is and what it is used for
2. What you need to know before you use TEMGESIC
3. How to take TEMGESIC
4. Possible side effects
5. How to store TEMGESIC
6. Contents of the pack and other information

1. What TEMGESIC is and what it is used for

This medicine has been prescribed for you for moderate to severe pain.

It contains buprenorphine which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you use TEMGESIC

Do not use TEMGESIC Sublingual Tablets and Injection

- If you are allergic (hypersensitive) to buprenorphine or any of the other ingredients of TEMGESIC Sublingual Tablets and Injections or to other opioids (medicines that are morphine- like in their action)
- If you have serious problems with your liver
- If you have serious breathing problems.

Warnings and precautions

Take special care with TEMGESIC Sublingual Tablets and Injection:

- If you suffer from seizures, fits or convulsions
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you feel you need to take more of TEMGESIC to get to the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- If you have problems with your liver

- If you have breathing problems or are taking medicines that may make your breathing slower or weaker
- Special care must be exercised in the elderly, where respiratory capacity may be reduced
- This product can cause sleepiness which may be increased by alcohol or anti-anxiety medicines.
- If you have depression or other conditions that are treated with antidepressants. The use of these medicines together with TEMGESIC can lead to serotonin syndrome, a potentially life-threatening condition (see Other medicines and TEMGESIC).

Advise your doctor in case of:

- recent head injury or brain disease,
- decrease of blood pressure,
- in men: urinary disorders (especially linked to enlarged prostate).

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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

Other medicines and TEMGESIC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

TEMGESIC should not be taken with:

- Medicines containing gestodene (a hormone)
- Antibiotic medicines (troleandomycin, rifampicin)
- Medicines to treat fungal infections (ketoconazole)
- Medicines for depression (norfluoxetine)
- Medicines for HIV infection (protease inhibitors: ritonavir, indinavir, saquinavir)
- Medicines for epilepsy (carbamazepine, phenytoin, phenobarbital)
- Other opioid medicines

Concomitant use of TEMGESIC and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and

may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe TEMGESIC together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

In particular you should also tell your doctor if you are taking:

- Medicines used to treat depression such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with TEMGESIC and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- Medicines to help you sleep (e.g., tranquillizers, hypnotics or sedatives).

TEMGESIC with food, drink and alcohol

Do not drink alcohol while you are taking TEMGESIC as it may make you feel drowsy.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take TEMGESIC if you are pregnant or think you might be pregnant.

If you use TEMGESIC during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take TEMGESIC while you are breastfeeding as buprenorphine passes into breast milk and will affect your baby.

Driving and using machines

TEMGESIC may cause drowsiness. If you feel tired, do not drive a motor vehicle or operate machinery.

TEMGESIC contains lactose/dextrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this product.

3. How to use TEMGESIC Sublingual Tablets and Injection

Do not share medicines prescribed for you with any other person.

Always use TEMGESIC exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

Your prescriber should have discussed with you, how long the course of tablets and injections will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

The usual dose is 1 to 2 TEMGESIC tablets to be dissolved under the tongue every 6 to 8 hours or as required. The tablet may require 5 to 10 minutes to dissolve and should not be chewed or swallowed.

The usual dose of the TEMGESIC Injections is 0,3 to 0,6 mg into a muscle or slowly into a vein repeated every 6 to 8 hours or as required.

TEMGESIC Sublingual Tablets and Injections are not recommended for use in children.

If you have the impression that the effect of TEMGESIC is too strong or too weak, talk to your doctor or pharmacist. Your doctor will tell you how long your treatment with TEMGESIC will last.

If you use more TEMGESIC Sublingual Tablets or Injection than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The expected symptoms of an overdose are drowsiness, nausea, vomiting and respiratory depression (difficulty breathing).

If you forget to take TEMGESIC

Do not take a double dose to make up for forgotten individual doses. If you missed a dose take it as soon as you remember unless it is time for your next dose.

If you stop taking TEMGESIC

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

4. Possible side effects

TEMGESIC can cause side effects.

Not all side effects reported for TEMGESIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your health care provider for advice.

Tell your doctor immediately if you experience any of the following symptoms after taking TEMGESIC.

You may need urgent medical attention or hospitalisation.

- If you get any sudden wheeziness, difficulty breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. These may be signs of an allergic reaction
- If you start to breathe more slowly or weakly than expected (respiratory depression)
- If you start to feel faint, as this may be a sign of low blood pressure

Other side-effects that may occur with TEMGESIC are:

- Effects on your liver: abnormal liver function; fever, loss of appetite, dark urine, yellowing of the eyes and skin.

- Effects on your stomach or intestine: feeling sick, being sick, diarrhoea.
- Effects on your nervous system: dizziness, hallucinations (sensing things that are not real), drowsiness, headaches, sweating, difficulty with balance and walking, tremor and impaired speech.
- Effects on your bladder: difficulty in urinating.
- Effects on your eyes: blurred vision.
- Dependence and addiction: frequency not known (cannot be estimated from the available data, see section “How do I know if I am addicted?”)
- Seizures: frequency not known (cannot be estimated from the available data)
- Drug Withdrawal: When you stop taking TEMGESIC you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking TEMGESIC, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TEMGESIC. For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store TEMGESIC

Store at or below 30 °C. Protect from light and moisture.

Store all medicines out of the reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets). Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What TEMGESIC contains

The active substance is:

TEMGESIC Sublingual Tablets: Each tablet contains 0,2 mg Buprenorphine (as hydrochloride).

The other ingredients are citric acid anhydrous, lactose monohydrate, magnesium stearate, maize starch, mannitol, povidone and sodium citrate.

TEMGESIC 1 ml Injection: Each 1 ml of TEMGESIC Injection contains 0,3 mg Buprenorphine (as hydrochloride) in a 5 % dextrose solution.

What TEMGESIC looks like and contents of the pack

TEMGESIC Sublingual Tablets are white bi-convex tablets engraved on one side with the letter “L”.

TEMGESIC 1 ml Injection is a colourless solution in clear glass ampoules of 1 ml.

TEMGESIC Sublingual Tablets:

Carton of 50 tablets, containing blister strips of 10 tablets each.

TEMGESIC 1 ml Injection:

A colourless solution in clear glass ampoules of 1 ml in packs of 5 ampoules.

Holder of Certificate of Registration

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