

PACKAGE LEAFLET: INFORMATION FOR THE USER

Temgesic 200 microgram Sublingual Tablets

Buprenorphine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet, See section 4.

What is in this leaflet:

1. What Temgesic is and what it is used for
2. What you need to know before you take Temgesic 200 microgram Sublingual Tablets
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1. WHAT TEMGESIC IS AND WHAT IT IS USED FOR

Temgesic 200 microgram Sublingual Tablets are strong pain killers that help lessen moderate or severe pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEMGESIC 200 MICROGRAM SUBLINGUAL TABLETS

Do not take Temgesic

- if you are allergic (hypersensitive) to buprenorphine (the active ingredient in Temgesic) or to other opiates or to any other component of the product (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Temgesic if you have:

- asthma or other breathing problems or are taking medicines which may make your breathing slower or weaker,
- an addiction or have ever been addicted to medicines or substances,
- problems with your liver, such as hepatitis,
- any kidney disease,
- low blood pressure,
- recently suffered from head injury or brain disease,
- thyroid problems,
- adrenocortical disorder such as Addison's disease,

- a urinary disorder such as an enlarged prostate or narrowing of the urethra.
- prostatic disease,
- are elderly
- a history of gallbladder disease
- acute abdominal pain
- alcohol problems
- curvature of the spine
- 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").

Important things to be aware of:

- **Misuse, abuse and diversion**

This medicine can be a target for people who abuse prescription medicines, and should be kept in a safe place to protect it from theft. **Do not give this medicine to anyone else.** It can cause death or otherwise harm them.

- **Breathing problems**

Some people have died from respiratory failure (inability to breathe) because they misused this medicine or took it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids.

- **Sleep-related breathing disorders**

Temgesic can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

- **Dependence**

This product can cause dependence.

- **Withdrawal symptoms**

This product can cause withdrawal symptoms if you are also taking other opioids such as heroin or methadone. Temgesic can also cause withdrawal symptoms if you stop taking it abruptly.

- **Diagnosis of unrelated medical conditions**

This medicine may mask pain symptoms that could assist in the diagnosis of some diseases. Do not forget to advise your doctor if you take this medicine.

Other medicines and Temgesic

Some medicines may increase the side effects of Temgesic and may cause various serious reactions. Do not take any medicines whilst taking Temgesic without talking to your doctor, especially:

- Benzodiazepines (used to treat anxiety or sleep disorders) such as diazepam, temazepam, or alprazolam. Your doctor will prescribe the correct dose for you. 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.

- **Other medicines that may make you feel sleepy which are** used to treat illnesses such as anxiety, sleeplessness, convulsions/seizures, or pain. These types of medicines will reduce your alertness levels making it difficult for you to drive and use machines. They may also cause a decreased heart rate and ability to breathe and may cause unconsciousness, which is very serious. Below is a list of examples of these types of medicines:
 - Other opioid containing medicines such as methadone, certain pain killers and cough suppressants.
 - Anti-depressants (used to treat depression) such as isocarboxazide, phenelzine, selegeline, tranylcypromine and valproate may increase the effects of this medicine.
 - Sedative H₁ receptor antagonists (used to treat allergic reactions) such as diphenhydramine and chlorphenamine.
 - Barbiturates (used to cause sleep or sedation) such as phenobarbital and secobarbital.
 - Tranquilisers (used to cause sleep or sedation) such as chloral hydrate.
- Anti-depressants, 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.
- Clonidine (used to treat high blood pressure) may extend the effects of this medicine.
- Naltrexone may prevent the therapeutic effects of Temgesic. If currently taking this medicine followed by concomitant use of naltrexone, you may experience a sudden onset of prolonged and intense withdrawal.
- Anti-retrovirals (used to treat AIDS) such as ritonavir, nelfinavir and indinavir may increase the effects of this medicine.
- Some antifungal agents (used to treat fungal infections) such as ketoconazole, itraconazole and certain antibiotics (macrolides) may extend the effects of this medicine.
- Some medicines may decrease the effect of Temgesic. These include medicines used to treat epilepsy (such as carbamazepine, phenobarbital, phenothiazines and phenytoin), and medicines used to treat tuberculosis (rifampicin).
- Anaesthetics (used during surgery such as halothane).

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

Temgesic with food, drink and alcohol

Do not take Temgesic together with alcohol. Alcohol may increase drowsiness and may increase the risk of respiratory failure if taken with Temgesic. Do not take Temgesic together with alcohol.

Pregnancy and breast-feeding

The risks of using Temgesic in pregnant women are not known. Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will decide if your treatment should be continued with an alternative medicine.

When taken during pregnancy, particularly late pregnancy, medicines like Temgesic may cause drug withdrawal symptoms including problems with breathing in your newborn baby. This may not appear until several days after birth.

Do not breast-feed whilst taking this medicine, since Temgesic passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Temgesic may cause drowsiness, particularly if you also drink alcohol or take sedative medicines. Do not drive, use any tools or machines, or perform dangerous activities until you know how this medicine affects you.

Temgesic 200 microgram Sublingual Tablets contains lactose and sodium.

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. HOW TO TAKE TEMGESIC 200 MICROGRAM SUBLINGUAL TABLETS

Always take Temgesic exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. **Do not take more tablets than your doctor has told you to.**

Use in adults

The usual dose for adults is 200-400 micrograms of Temgesic every 6-8 hours, or as required.

Use in children and adolescents over 50kg

The usual dose is 200-400 micrograms of Temgesic every 6-8 hours, or as required.

Children over 37.5 kg:

Children weighing more than 37.5 kg and who are able to use a sublingual tablet, treatment can be started with one Temgesic 200 microgram sublingual tablet. The dose can be repeated every 6 to 8 hours.

The tablets should lie under the tongue until dissolved, which occurs in 5 to 10 minutes. They should not be chewed or swallowed. The dose may be repeated every 6-8. hour. Temgesic 400 microgram tablets should not be used in children.

Temgesic sublingual tablet should be not used for children weighing less than 37.5 kg.

Fixed intervals or daily doses should not be prescribed until an appropriate dosing interval is determined by clinical observation of the child.

Place the tablet under your tongue and let it dissolve, **which happens within 5 to 10 minutes** do not swallow or chew the tablet.

If you take more Temgesic than you should

If you or someone else take too much of this medicine, you must go or be taken immediately to an emergency centre or hospital for treatment as **overdose** with Temgesic may cause serious and life-threatening breathing problems.

Symptoms of overdose may include feeling sleepy, low blood pressure (hypotension), nausea (feeling sick), vomiting, constricted pupils (small pupils characterized by blurred vision and difficulty focusing) and you may breathe much slower than is normal for you.

If you forget to take Temgesic

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Temgesic can cause side effects, although not everybody gets them.

Tell your doctor immediately or you must go or be taken immediately to an emergency centre or hospital if you experience any of the following symptoms after taking this medicine. These symptoms can be serious and Temgesic may cause serious and life-threatening breathing problems:

- If you start to breathe more slowly or weakly than usual. This may be a sign of respiratory depression induced by Temgesic (affects an unknown number of people).
- If you get any sudden wheezing, 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 (rare side effect that may affect up to 1 in 1,000 people).
- If you start to feel faint, as this may be a sign of low blood pressure (common side effect that may affect up to 1 in 10 people).
- If you get sudden constriction of the airways (bronchial spasm) (affects an unknown number of people).
- If you get a sensitivity reaction with fever, skin rash, swelling and sometimes decreased blood pressure (anaphylactic shock) (affects an unknown number of people).
- If you get a swollen face, tongue, or throat, or difficulties to swallow, hives and difficulties to breathe (angioedema) (affects an unknown number of people).

Other side effects that may occur with Temgesic are presented below:

<i>Very common side effects (may affect more than 1 in 10 people):</i>
Sedation, dizziness, nausea (feeling sick), loss of balance and/or giddiness (vertigo).
<i>Common side effects (may affect up to 1 in 10 people):</i>
Headache, miosis (small pupils), hypoventilation (shallow or slow breathing), vomiting, hyperhidrosis (increased sweating), low blood pressure.
<i>Uncommon side effects (may affect up to 1 in 100 people):</i>

State of confusion, euphoric mood (exaggerated feeling of well- being), nervousness, depression, psychotic disorder (mental disorder causing abnormal thinking and perceptions), hallucination, depersonalisation (not feeling like yourself), dysarthria (speech disorder), paraesthesia (pins and needles), coma, tremor, blurred vision, diplopia (double vision), visual impairment, conjunctivitis (infection of the eye), tinnitus (ringing of the ears), tachycardia (fast heartbeat) bradycardia (slow heartbeat), cyanosis (blue or purple discoloration of the skin), second degree atrioventricular block (heart condition), hypertension (high blood pressure), pallor (pale skin), dyspnoea (shortness of breath), apnoea (pauses in breathing), dry mouth, constipation, dyspepsia (indigestion), flatulence, pruritus (itching), rash, urinary retention, asthenia (feeling weak), fatigue, malaise (feeling of discomfort).
<i>Rare side effects (may affect up to 1 in 1000 people):</i>
Decreased appetite, dysphoria (feeling unwell or unhappy), agitation, convulsion (fits), abnormal coordination, diarrhoea, urticaria (hives), allergy (hypersensitivity).
<i>Not known (frequency cannot be estimated from the available data):</i>
Drug dependence, somnolence, drug ineffective, drug interaction.

Experience of the use of Temgesic in patients have also identified the following reactions and/or side effects:

Serious allergic reaction, confusional state, drug dependence, hallucination, sleepiness, dizziness, headache, low blood pressure, very slow breathing rate (respiratory depression), shortness of breath (Bronchospasm), nausea, vomiting, itching, rash, excessive sweating, swelling under the skin, medicine not working, medicine affected by another medicine, tiredness.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. HOW TO STORE TEMGESIC 200 MICROGRAM SUBLINGUAL TABLETS

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package

Do not use the tablets after the expiry date (EXP month/year) shown on the pack.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Temgesic tablets contain

The active substance is buprenorphine hydrochloride

The other ingredients are lactose, mannitol, maize starch, povidone K30, citric acid anhydrous, magnesium stearate and sodium citrate

What Temgesic tablets look like and contents of the pack

The tablets come in cartons containing five strips of 10 tablets each, a total of 50 tablets. The tablet is white and has “L” on one side.

Marketing Authorisation Holder

EUMEDICA Pharmaceuticals GmbH

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