

PACKAGE LEAFLET: INFORMATION FOR THE USER

Temgesic 200 microgram sublingual tablets
Temgesic 400 microgram sublingual tablets

buprenorphine hydrochloride

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 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 possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Temgesic Sublingual Tablets are and what they are used for
2. What you need to know before you take Temgesic Sublingual Tablets
3. How to take Temgesic Sublingual Tablets
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5. How to store Temgesic Sublingual Tablets
6. Contents of the pack and other information

1. WHAT TEMGESIC SUBLINGUAL TABLETS ARE AND WHAT THEY ARE USED FOR

This medicine has been prescribed for you and is a strong pain killer that helps lessen moderate or 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 TAKE TEMGESIC SUBLINGUAL TABLETS

Do not take Temgesic

If you are allergic to buprenorphine, to any of the other ingredients of this medicine (listed in section 6) or to other opiates (drugs which are morphine – like in their action).

Warnings and precautions

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

- Suffer from seizures, fits or convulsions.
- Are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- Have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

- Feel you need to take more of Temgesic to get 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.
- Have problems with your liver.
- Have breathing problems or are taking medicines with may make your breathing slower or weaker.
- 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”).

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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.

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

- Medicines used to treat depression known as monoamine oxidase inhibitors (examples include tranylcypromine, phenelzine).
- 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.

- Medicines to help you sleep (for example tranquilisers, hypnotics or sedatives).
- Sedative medicines such as benzodiazepines or related drugs:
Concomitant use of Temgesic and sedative medicines such as benzodiazepines or related drugs 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.

You should visit your doctor regularly whilst you are taking these medicines at the same time as Temgesic.

Temgesic Sublingual Tablets with alcohol

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

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

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

Driving and using machines

If you feel drowsy while taking these tablets do not drive or use machines.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

The new driving offence concerning driving after drugs have been taken applies in Great Britain. There is further information for patients who are intending to drive in Great Britain available at: <https://www.gov.uk/drug-driving-law>

Temgesic contains lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. HOW TO TAKE TEMGESIC SUBLINGUAL TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. **Do not take more tablets than your doctor has told you to.**

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

Adults and children over 12 years of age

The usual dose is one or two 200 microgram tablets every six to eight hours or one 400 microgram tablet every six to eight hours, or as required. Place the tablet under your tongue and let it dissolve.

Do not swallow or chew the tablet.

Children between 6 years and 12 years of age

The dose depends on their weight and your doctor will tell you the correct dose for your child.

This product will not be given to infants and children under 6 years of age.

If you take more Temgesic Sublingual Tablets than you should

If you accidentally take too many tablets you must get medical help at once. Take any remaining medication, the carton and the leaflet with you when seeking medical attention.

If you forget to take Temgesic Sublingual Tablets

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.

If you stop taking Temgesic Sublingual Tablets

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

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

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are rare, these symptoms can be serious

- 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 breath 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 stomach or intestine:** feeling sick, being sick.
- **Effects on your nervous system:** dizziness, hallucinations (sensing things that are not real), drowsiness, headaches, sweating.
- **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.

Side effects that may occur when buprenorphine is used as substitution treatment are fever, diarrhoea, loss of appetite, dark urine, yellowing of the eyes and skin, difficulty with balance and walking, tremor and impaired speech.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TEMGESIC SUBLINGUAL TABLETS

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

Do not store above 30°C.

Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Temgesic Sublingual Tablets contain

The active substance is buprenorphine hydrochloride.

The other ingredients are lactose, mannitol, maize starch, povidone K30, citric acid anhydrous, magnesium stearate, sodium citrate, purified water and ethanol (96%).

What Temgesic Sublingual Tablets look like and contents of the pack

Temgesic 200 microgram Sublingual Tablets are round white tablets, marked with an L on one side.

Temgesic 400 microgram Sublingual Tablets are round white tablets, marked with an H on one side.

The sublingual tablets come in cartons containing five strips of 10 tablets each, a total of 50 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Indivior UK Limited
The Chapleo Building
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Manufacturer:

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