

PACKAGE LEAFLET: INFORMATION FOR THE USER

Temgesic 200 microgram

Buprenorphine hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Temgesic Sublingual Tablets are and what they are used for
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1. WHAT TEMGESIC SUBLINGUAL TABLETS ARE AND WHAT THEY ARE USED FOR

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

2. BEFORE YOU TAKE TEMGESIC SUBLINGUAL TABLETS

Do not take Temgesic

If you are allergic (hypersensitive) to buprenorphine, to any of the other ingredients of Temgesic Sublingual Tablets (see section 6 'Further Information') or to other opiates (drugs which are morphine – like in their action).

Take special care with Temgesic Sublingual Tablets

Before starting treatment with Temgesic, contact your doctor if you:

- Are or have ever been addicted to medicines or substances;
- Have problems with your liver;
- Have breathing problems or are taking medicines which may make your breathing slower or weaker.

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

Taking 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.

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

- Medicines used to treat depression known as monoamine oxidase inhibitors (examples include tranylcypromide, phenelzine);
- Medicines to help you sleep (for example tranquilisers, hypnotics or sedatives).

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Temgesic Sublingual Tablets with food and drink

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

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or breast-feeding before taking Temgesic.

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

Driving and using machines

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

Important information about some of the ingredients of Temgesic Sublingual Tablets

Temgesic tablets contain lactose (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.

3. HOW TO TAKE TEMGESIC 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.**

Adults and children over 12 years of age

The usual dose is one or two 200 microgram tablets 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Temgesic 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

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.

5. HOW TO STORE TEMGESIC SUBLINGUAL TABLETS

Keep out of the reach and sight of children.

The tablets should be stored below 30°C in the original package.

Do not take Temgesic tablets after the expiry date which is stated on the pack (EXP month/year). The expiry date refers to the last day of that month.

Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 tablets are round white tablets, marked with an L on one side and a sword on the other.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

RB Pharmaceuticals Limited
103-105 Bath Road
Slough
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Manufacturer:

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