

Temazepam 10mg Tablets/Temazepam 20mg Tablets

Your medicine is known by the either of above names but will be referred to as Temazepam throughout this:

Patient Information Leaflet

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1) What Temazepam is and what it is used for
- 2) What you need to know before you take Temazepam
- 3) How to take Temazepam
- 4) Possible side effects
- 5) How to store Temazepam
- 6) Contents of the pack and further information

1) What Temazepam is and what it is used for

Temazepam is an anti-anxiety drug which is used in the short-term to help people sleep. It belongs to a group of drugs called benzodiazepines.

Temazepam is used for:

- short-term treatment of insomnia (difficulty in sleeping) which is severe, disabling or causing extreme distress
- pre-medication before minor surgery or other procedures.

2) What you need to know before you take Temazepam

Do not take Temazepam if you:

- are allergic to temazepam or other benzodiazepines (e.g. diazepam) or any of the other ingredients of this medicine (listed in section 6)
- have difficulty in breathing or lung problems
- have a condition called sleep apnoea syndrome (where breathing stops during sleep)
- have myasthenia gravis (a condition where the muscles become weak and tire easily)
- have severe liver problems
- have a history of mental illness, such as obsessions or phobias (irrational fears)
- suffer from anxiety or psychotic illness. Temazepam tablets may unmask or worsen symptoms
- are breast-feeding
- are a child under the age of 18 years.

Warnings and precautions

Talk to your doctor before taking this medicine if you:

- are elderly or frail. If you get up at night, take care as there is an increased risk of falling and consequently of hip fractures due to muscle relaxant effect of the tablets
- have long-term lung, kidney or liver problems
- have history of breathing problems. Whilst taking Temazepam tablets your breathing may become less forceful
- have a history of problems with alcohol or drug abuse (your risk of dependence is higher)
- suffer from mental illness, depression or depression with anxiety
- have recently suffered a bereavement (if Temazepam is taken to help sleep during periods of bereavement it may stop you coming to terms with the loss)
- are or suspect that you are pregnant.

Other medicines and Temazepam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Temazepam tablets may influence the effect and/or side effects of other medicines. If you see another doctor or go into hospital, particularly if you are having an operation under anaesthesia tell the doctor which medicines you use.

The following medicines may increase the sedating effect of Temazepam tablets:

- medicines to treat mental illness (antipsychotics), such as clozapine
- medicines to treat depression, such as phenelzine and amitriptyline
- other sleeping pills, such as zopiclone
- anxiolytic or sedative drugs, such as diazepam
- narcotics (strong pain killers) such as codeine, morphine. Feelings of excitement (euphoria) may increase, which in turn increase the chance on physical or mental dependence
- medicines used to treat epilepsy
- anaesthetics (used during surgery)
- sedative antihistamines, such as promethazine
- medicines used to treat high blood pressure, such as doxazosin and lofexidine
- nabilone (used to treat vomiting and nausea).
- cisapride (used for stomach disorders)
- muscle relaxants, such as baclofen and tizanidine.

Concomitant use of Temazepam and opioids (strong pain killers, medicines for substitution therapy and some cough 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 Temazepam together with opioids the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid 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.

Zidovudine and ritonavir (retroantiviral drugs used to treat HIV infection and AIDS) – may cause an increase in concentration of temazepam in the blood.

Theophylline (used to treat asthma) – may decrease the effect of temazepam.

Disulfiram (used to treat alcohol dependence) – inhibits the metabolism of temazepam and increases the risk of temazepam poisoning.

Fluvoxamine (used to treat depression) – increases the concentration of temazepam in the blood.

Cimetidine (used to treat stomach ulcers) – decreases the blood concentration of temazepam in the blood.

Rifampicin (an antibacterial drug) – increases the metabolism of temazepam and decreases the temazepam blood concentration.

Temazepam:

- increases or decreases the level of phenytoin
- increases the effects of sodium oxybate (used to treat narcolepsy with cataplexy – sleep disorders with sudden and transient loss of muscle tone).
- possibly reduces the effects of levodopa (used to treat Parkinson's disease).
- enhances the blood pressure lowering effect of anti-hypersensitive medicines (e.g. moxonidine, beta-blockers).

Important safety messages about Temazepam:

- When taking this medicine there is a risk of dependence (a need to keep taking the medicine). The risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse, or suffer from a personality disorder.
- Close medical supervision is required when taking this medicine. Your doctor will ensure that you take the lowest effective dose and this should be taken for the shortest possible time and not exceed 4 weeks.
- You may become tolerant to the effects of Temazepam after you have been taking it repeatedly for a few weeks (see section 3, **How to take Temazepam**).
- When stopping this medicine you may experience withdrawal effects (see section 3, **If you stop taking Temazepam**).
- Behavioural effects may occur while taking Temazepam (see section 4, **Possible Side Effects**).
- To reduce the risk of amnesia (loss of memory), you should make sure that you are able to have an uninterrupted sleep of at least 7-8 hours.
- If you have been given Temazepam for premedication, you should be accompanied home.

Temazepam with food and drink

Do NOT drink alcohol while taking these tablets, as taken together they could make you feel very drowsy which could be dangerous.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, and breathing and feeding difficulties. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms.

Driving and using machines

Your tablets may make you feel drowsy during the day, make you forgetful and impair your concentration, vision and muscle function. Also you will be less alert if you have not been able to sleep for long enough. If affected, do NOT drive or operate machinery.

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.

Important information about some of the ingredients of Temazepam

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 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 Temazepam

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. You will be given the lowest effective dose for the shortest possible time.

The tablets should be swallowed preferably with a glass of water.

Your doctor will decide the correct dosage; the recommended dose is:

Insomnia

- **Adults:** 10-20 mg should be taken when going to bed or up to 30 minutes before going to bed.

Very occasionally, the dose may be increased to 30-40 mg daily.

- **Elderly patients:** the dose is 10 mg daily. Very occasionally, this may be increased to 20 mg daily.

- **Children:** Temazepam is NOT recommended for use in children under the age of 18 years.

For patients who have certain problems with blood vessels or their liver the dosage may be lower.

Do NOT change the dose yourself.

Premedication

- **Adults:** 20-40 mg should be taken 30-60 minutes before surgery.
- **Elderly:** Lower doses may be required by elderly patients, up to half the normal adult dose may be adequate.
- **Children:** Temazepam is not recommended for use in children under the age of 18 years.

If you take more Temazepam than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause drowsiness, difficulty in controlling movements, slurred speech and involuntary eye movements; coma, low blood pressure and breathing problems can also occur.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Temazepam

If you fall asleep without having taken a dose and wake up some hours later, do not take the missed dose. If necessary, return to your normal dose schedule the following night. Do not take a double dose to make up for a forgotten dose.

If you stop taking Temazepam

You will be told by your doctor to stop taking the tablets as soon as is possible and the dose will be reduced gradually. You should not stop taking the tablets suddenly or without medical advice.

If the tablets are stopped abruptly or the dose reduced too rapidly you may get unpleasant effects.

These withdrawal effects can include headache, muscle pain, tension, severe anxiety, confusion, depression, restlessness, irritability and sweating. In severe cases of withdrawal you may experience a feeling of things being unreal, a feeling of detachment from your surroundings, numbness and tingling in the hands and feet, sounds seeming to be louder than usual and which can sometimes be painful if the sound is loud, sensitivity to light or touch, hallucinations, involuntary movements, being sick (vomiting) and fits. In addition, problems with sleeping, feeling restless and anxious and mood changes may return.

If you experience these or any other unusual effects when you stop taking Temazepam, speak to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4) Possible side effects

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

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you suffer from:

- behavioural changes such as restlessness, agitation, irritability, aggressiveness, delusions, excitement, rages, nightmares, hallucinations, confusion, psychiatric disorders and inappropriate behaviour, as your treatment may be stopped; you are more likely to suffer these effects if you are elderly.

The following side effects are common at the beginning of therapy. These effects are often mild and usually wear off after a few days treatment:

- daytime drowsiness or drowsiness the following day
- reduced alertness
- loss of co-ordination
- numbed emotions
- confusion
- tiredness
- dizziness
- muscle weakness
- double vision
- light-headedness.

The following rare effects may also occur:

- skin reactions e.g. rash
- headache
- spinning sensation (vertigo)
- stomach upset (indigestion, diarrhoea, constipation)
- vivid dreams or nightmares
- sleep disturbance
- changes in sex drive
- depression
- impaired muscular function
- dry mouth
- memory loss
- yellowing of your skin or the whites of your eyes (jaundice)
- difficulty passing urine leading to pain and discomfort
- low blood pressure
- a very fast, uneven or forceful heartbeat (palpitation)
- salivation changes
- visual disturbance
- slurred speech (dysarthria)
- shaking
- incontinence
- blood disorders
- abnormal results in liver function tests.

Use (even at therapeutic dosages) may lead to physical dependence; sudden discontinuation of treatment may result in withdrawal effects and recurrence of problems.

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 at:

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 Temazepam

- **Keep out of the sight and reach of children.**
- Do not store above 25°C. Store in the original package to protect from light.
- Do not use Temazepam after the expiry date that is stated on the carton and blister. The expiry date refers to the last day of that month.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines 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 protect the environment.

6) Contents of the pack and further information

What Temazepam tablets contain

- The active ingredient is temazepam.
- Each tablet contains 10mg or 20mg of temazepam.
- The other ingredients are lactose anhydrous, cellulose microcrystalline, titanium dioxide E171, croscarmellose sodium and magnesium stearate.

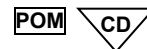
What Temazepam looks like and contents of the pack

Temazepam Tablets 10 mg is a white to pale yellow, flat, round tablets with a break-line on one side and "5K1" on the reverse.

Temazepam Tablets 20 mg is a white to pale yellow, flat, round tablets with a break-line on one side and "5K2" on the reverse.

Temazepam is available as blister packs of 28 tablets.

PL 46420/0357 Temazepam 10mg Tablets



PL 46420/0358 Temazepam 20mg Tablets

Who makes and repackages your medicine?

Your medicine is manufactured by Teva Pharmaceutical Works Private Limited Company, Pallagi ut 13, 4042 Debrecen, Hungary or Merckle GmbH, Ludwig-Merckle-Strasse 3, D-89143 Blaubeuren, Germany. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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For any information about the medicine, or to request for a copy of this leaflet in Braille, large print or audio, please call the PL holder Suerte Pharma Limited on 020 8839 3000.