

Temazepam 10mg and 20mg Tablets

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 Temazepam tablets are and what they are used for
- 2 What you need to know before you take Temazepam tablets
- 3 How to take Temazepam tablets
- 4 Possible side effects
- 5 How to store Temazepam tablets
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1 What Temazepam tablets are and what they are used for

Temazepam tablets are sedatives which may be used:

- for the short-term treatment of insomnia (difficulty sleeping), which is severe, disabling or distressing
- as a pre-medication before minor surgery or investigative procedures, especially when hospital admission is not required.

2 What you need to know before you take

Temazepam tablets

Do not take Temazepam tablets if you:

- are **allergic** to temazepam or any of the ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swallowing or swelling of the face, lips, throat or tongue (see section 6 for list of ingredients)
- are **under 18 years of age**
- have any **long-term mental illness** including obsessions or phobias (irrational fears)
- suffer from **anxiety** with depression or as the only treatment for depression (as treatment with temazepam may unmask depression or worsen existing depression, or suicidal thoughts)
- suffer from sudden or severe **breathing problems**
- have **severe liver** disease
- suffer from muscle weakness (**myasthenia gravis**)
- suffer from **glaucoma** (increased pressure in the eye)
- suffer from a condition where you stop breathing temporarily while asleep (**sleep apnoea**).

Warnings and precautions

Talk to your doctor before taking Temazepam tablets if you:

- have any **mental illness** such as depression or personality disorders
- have suffered a **loss or bereavement** (temazepam can affect the way in which you react to this)
- have any long-term **kidney** or **liver** problems
- have a history of **alcoholism** or **drug abuse**
- are **elderly**
- are **pregnant** (see Pregnancy and breast-feeding)
- are due to have **surgery**.

Other considerations

- **Dependence** - when taking this medicine there is a risk of dependence, which increases with the dose and length of treatment and also in patients with a history of alcoholism and drug abuse.
- **Tolerance** - if after a few weeks, you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor.
- **Withdrawal** - treatment should be gradually withdrawn. Withdrawal symptoms may occur with Temazepam tablets even when normal doses are given for short periods of time. See Section 3, 'If you stop taking Temazepam tablets'.

- **Psychiatric and paradoxical reactions** - when taking this medicine there is a risk of adverse behavioural effects (see section 4 Possible side effects), which are more likely to occur in children and the elderly. This includes complex **sleep behaviour**-related events such as 'sleep-driving', due to the risk posed to yourself and others you must **talk to your doctor immediately** if this occurs.
- **Memory loss** may be experienced several hours after taking temazepam. If possible, to reduce the risk allow 7 to 8 hours of uninterrupted sleep after taking.

Children

Do not give this medicine to children 18 years old or under.

Other medicines and Temazepam tablets

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

- sodium oxybate used to treat narcolepsy. Do not use concomitantly with Temazepam tablets
- other medicines which act on the brain causing sedation including:
 - medicines to treat severe mental illness e.g. chlorpromazine, olanzapine
 - strong painkillers e.g. morphine. Concomitant use of Temazepam tablets 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 tablets 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.
 - medicines to treat depression or anxiety e.g. fluvoxamine
 - medicines to make you sleep
 - anaesthetics
 - sedative antihistamines
 - lofexidine and nabilone
 - medicines which lower high blood pressure (in particular monoxidine or alpha blockers)
 - muscle relaxants (baclofen and tizanidine)
 - disulfiram used to treat alcoholism
- cisapride used to treat gastric reflux
- rifampicin used to treat infections
- cimetidine used to treat stomach ulcers
- medicines to treat epilepsy (e.g. hydantoins (e.g. phenytoin), or barbiturates)
- antivirals (e.g. zidovudine and ritonavir)
- theophylline used to treat respiratory diseases
- medicines used to treat Parkinsonism (e.g. levodopa)
- clozapine used to treat schizophrenia.

Temazepam tablets with alcohol

Do not drink alcohol while you are taking Temazepam tablets. Alcohol may increase the sedative effects and make you very sleepy.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, breast-feeding, think you may be pregnant, or are planning to have a baby. If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby may develop symptoms such as low body temperature, floppiness, and breathing and feeding difficulties or withdrawal symptoms (see section 3 'If you stop taking Temazepam tablets').

Driving and using machines

Temazepam tablets may make you sleepy or affect your concentration, vision, memory or muscle function. This may affect your performance at skilled tasks e.g. driving and operating machinery. These effects may still occur the next day. Make sure you are not affected before you 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.

Temazepam tablets contain lactose

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

3 How to take Temazepam tablets

The recommended dose is:

Adults:

- **Insomnia** - 10-20mg before going to bed. Your doctor may increase this to 30-40mg. Long term use of temazepam is not recommended. Improvement is often noticed after a short time and treatment should not usually exceed 4 weeks. However, in some cases your doctor may advise you to continue treatment for at least 6 months.
- **Before surgery** - 20-40mg half to one hour before surgery or investigative procedures. It is recommended that you should be accompanied home if you receive temazepam treatment before surgery or investigative procedures.

Elderly and patients with brain and blood-vessel-related disease: Half the above adult doses. It is important to take this medicine exactly as directed by the doctor.

Children and adolescents: Not recommended for children less than 18 years old.

Patients with breathing difficulties: A lower dose is recommended.

Do not alter the dose or stop treatment without asking your doctor. See section 2 for information on tolerance and dependence.

Swallow the tablets whole with a glass of water.

Always take Temazepam tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you take more Temazepam tablets than you should

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Signs of overdose include drowsiness, confusion, weakness, unusual behaviour and, in more serious cases, convulsions, lack of coordination or muscle tension, low blood pressure, breathing difficulties, coma and very rarely death.

If you forget to take Temazepam tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Temazepam tablets

- If you stop taking Temazepam tablets suddenly, you may experience unpleasant withdrawal effects including: depression, nervousness, confusion, tension, headache, anxiety, dizziness, loss of concentration or appetite, tremor, feeling or being sick, ringing in the ears, stomach cramps, heart or blood pressure disturbances, sleeplessness, irritability, sweating and diarrhoea, derealisation (feeling of unreality to the world around), depersonalisation (feeling of unreality to self, that the mind is separated from body), hallucinations, painful sensitivity to sound, loss of feeling and tingling of the hands and feet, hypersensitivity to light, noise and physical contact, muscle pain and restlessness.
- Do not stop taking your medicine without telling your doctor as they may wish to gradually reduce the number of tablets you take before stopping them completely.
- Treatment should be gradually withdrawn to prevent the symptoms you are being treated for from returning more severely than before (rebound insomnia) and to prevent you experiencing anxiety (rebound anxiety) and other symptoms such as mood changes, restlessness or changes in sleep patterns.
- You may also experience vivid dreams and broken sleep for some weeks after withdrawal.

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, particularly when you first start taking it, although not everybody gets them.

Stop treatment and contact a doctor at once if you have the following symptoms of an allergic reaction

- itchy skin, rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Effects more common at the start of therapy:** drowsiness, light-headedness, numbed emotions, reduced alertness, confusion, impaired muscle coordination (especially in the elderly), fatigue, headache, dizziness, muscle weakness, lack of co-ordination, double vision, slow and shallow breathing (respiratory depression), slurred speech or breathing difficulties.
- **Psychological effects:** restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, dreams, restless sleep, hallucinations (seeing things that are not real), mental illness (psychoses causing mood swings, depression, paranoia), other adverse behavioural effects, amnesia associated with inappropriate behaviour, dependence, abuse. These effects may be quite severe and are more likely to occur in children and the elderly.
- **Other effects:** vertigo, stomach upset, changes in sexual desire, skin rashes, difficulty passing water, dry mouth, tremor, loss of bladder control, sight problems, increase in the amount of saliva, low blood pressure, memory loss, difficulty speaking, palpitations. Jaundice (yellowing of the skin or eyes), sore throats, infections, bruising or nose bleeds may be signs of changes in the number and types of blood cells so your doctor may wish to give you a blood test.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 tablets

Keep out of the sight and reach of children.

Store the tablets below 25°C. Store in the original package to protect from moisture. Keep the blister in the outer carton to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after EXP. 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 protect the environment.

6 Contents of the pack and other information

What Temazepam tablets contain:

- The active substance (the ingredient that makes the tablet work) is temazepam.
- Each tablet contains either 10mg or 20mg of temazepam.
- The other ingredients are: lactose, maize starch, povidone, magnesium stearate and colloidal silica.

What Temazepam tablets look like and contents of the pack:

Temazepam 10mg Tablets are white to pale yellow, circular, flat bevelled-edge uncoated tablets impressed "C" and the identifying letters "ZM" on either side of a central division line on one face and blank on the reverse.

Temazepam 20mg Tablets are white to pale yellow, circular, flat bevelled-edge uncoated tablets impressed "C" and the identifying letters "ZN" on either side of a central division line on one face and blank on the reverse.

Pack size 28 tablets

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK.

Manufacturer

Surepharm Services Limited, Unit 2H, Bretby Business Park, Ashby Road East, Bretby, Burton-on-Trent, DE15 0YZ, United Kingdom

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