Package leaflet: Information for the user

Temazepam Tablets 10 mg and 20 mg

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.

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
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1. What Temazepam tablets are and what they are used for

Temazepam tablets are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness.

They may be used for short term treatment of difficulty in sleeping (insomnia) which is severe, disabling or causing great distress.

They can also be used as a sedative prior to minor surgery or similar 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 active substance, to other benzodiazepines or any of the other 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.
- are **18 years of age or under**.
- have **severe liver** problems.
- suffer from **breathing problems whilst sleeping** (sleep apnoea).
- suffer from severe **muscle weakness** (myasthenia gravis).
- suffer from sudden or severe **breathing problems**.

- have any **long term mental illness** including obsessions or phobias (irrational fears).
- suffer from **anxiety** with or without depression or psychotic illness. Temazepam tablets may unmask or worsen symptoms
- are **breast-feeding**.
- suffer from **glaucoma** (increased pressure in the eye).

Warnings and precautions
Talk to your doctor or pharmacist before taking Temazepam tablets 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 the muscle relaxant effect of the tablets.
- 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 breathing problems.** Whilst taking Temazepam tablets your breathing may become less forceful.
- suffer from or have a history of **depression.**
- have or have ever had a history of or tendency to **alcohol or drug abuse** (see "Dependence" below).
- are or suspect that you are **pregnant.**
- suffer from a **personality disorder.**
- suffer from **muscle weakness.**

Please tell your doctor if you have any of the conditions listed above.

Other considerations
- **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 go and see your doctor as an adjustment to your dosage may be required.
- **Dependence** - when taking this type of medicine there is a risk of dependence, which increases with dose and length of treatment. There is a greater risk in patients with a history of alcohol or drug abuse.
- **Withdrawal** - treatment should be gradually withdrawn. Withdrawal symptoms occur with Temazepam tablets even when normal doses are given for short periods of time. See Section 3, **"If you stop taking Temazepam tablets"**.
- **Memory loss** may be experienced several hours after taking temazepam. If possible, to reduce the risk allow 7-8 hours of uninterrupted sleep after taking Temazepam tablets.
- **Psychiatric and "paradoxical" reactions** - Temazepam tablets can cause behavioural side effects such as restlessness, agitation, irritability, aggressiveness, delusions (false beliefs), rages, nightmares, hallucinations, psychoses, sleepwalking, inappropriate behaviour, increased insomnia and other adverse behavioural effects.

- **Minor surgery** – if you have been given Temazepam tablets as a sedative prior to minor surgery you should make arrangements to be accompanied home.
- **Sleep behaviour** - complex sleep behaviour-related events such as "sleep driving" (driving while not fully awake with no memory of the event) have been reported in patients taking temazepam. The risk of these behaviours increases when alcohol is consumed. Tell your doctor immediately if you suffer from any sleep behaviour-related events as your medicine may need to be changed.

Other medicines and Temazepam Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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.

Check with your doctor or pharmacist if you are taking any of the following:
- medicines to treat severe mental illness e.g. chlorpromazine, olanzapine
- medicines to treat depression or anxiety e.g. amitriptyline, fluoxetine, phenelzine
- medicines to make you sleep e.g. diazepam, zolpidem
- medicines to treat anxiety and other tranquillizers
- strong pain killers e.g. codeine, morphine.
- medicines used to treat epilepsy (hydantoins, phenytoin, or barbiturates)
- anaesthetics (used during surgery)
- antihistamine medicines which cause sleepiness e.g. chorphenamine
- lofexidine and nabilone
- antivirals e.g. zidovudine and ritonavir
- theophylline used to treat asthma
- muscle relaxants (baclofen and tizanidine)
- disulfiram used to treat alcoholism
- fluvoxamine used to treat depression
- cimetidine used to treat stomach ulcers
- rifampicin an antibacterial drug.
- sodium oxybate used to treat narcolepsy with cataplexy - sleep disorders with sudden and transient loss of muscle tone.
- levodopa used to treat Parkinson's disease
- antihypertensive medicines (e.g. moxonidine, alpha blockers (e.g. doxazosin), beta-blockers) - enhanced blood pressure lowering effect.
- clozapine used to treat schizophrenia.

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.

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

Pregnancy and breast-feeding
Do not take this medicine 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. It is especially important not to use Temazepam tablets during the first three months of pregnancy. If for urgent medical reasons, Temazepam tablets are taken during late pregnancy or during labour the baby may show withdrawal symptoms (low body temperature, floppiness and breathing and feeding difficulties) after birth because of physical dependence (see section. 3 "If you stop taking Temazepam tablets").

Temazepam will appear in breast milk in small amounts, therefore breast-feeding mothers should not take this medicine.

Driving and using machines
Temazepam tablets may make you feel drowsy or affect your concentration, vision, memory or muscle function. This feeling may persist the next day or be even worse when you sleep for less than 7 to 8 hours after taking your medication.

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 you have an intolerance to some sugars, tell your doctor or pharmacist before taking this medicine.

3. How to take Temazepam tablets

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

The tablet should be taken together with liquid.

The recommended dose is:

Insomnia
- **Adults:** 10 mg to 20 mg taken at bedtime. This dose must not be exceeded. In extreme cases the dose may be increased to 30 mg - 40 mg by your doctor.
- **Elderly or frail patients and patients with brain and blood-vessel-related disease or liver or kidney disease:** Half the above adult dose. A lower dose of 5 mg at night may be used. This dose may be increased to 10 mg or in extreme cases to 20 mg, by your doctor.

Before surgery
- **Adults:** 20 mg to 40 mg taken one hour before the procedure.
- **Elderly:** Half the above adult dose - 10 mg to 20 mg taken one hour before the procedure.

Children and adolescents
Temazepam tablets are not intended for patients under 18 years of age.

Patients with breathing difficulties
A lower dose is recommended.

If after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should go and see your doctor as an adjustment to your dosage may be required. **Do not alter the dose or stop treatment without asking your doctor.** See section 2 for information on tolerance and dependence.

How long should you take Temazepam tablets?
The duration of administration should be as short as possible. In general, it could be a few days up to 2 weeks and not exceed 4 weeks, the stepwise withdrawal phase included. Your doctor will choose a withdrawal regime based on your individual needs.
Certain situations may require prolongation beyond the maximum time of treatment. Your attending doctor will decide on that after renewed evaluation of your complaints.

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 if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Do not go unaccompanied to seek medical help. Signs of overdose include drowsiness, confusion, weakness and, in more serious cases, lack of coordination or muscle tension, low blood pressure, breathing difficulties, coma and very rarely death.

If you forget to take Temazepam tablets
If you forget to take a dose at bedtime but remember during the night, only take the missed dose if you are still able to have 7-8 hours of uninterrupted sleep. If this is not possible, take the next dose before bed time the next night.
Do not take a double dose to make up for a forgotten tablet. If you are worried ask your pharmacist or doctor for advice.

If you stop taking Temazepam tablets
- Treatment should be gradually withdrawn as the symptoms you are treated for will return more intense than before (rebound insomnia), also anxiety (rebound anxiety), restlessness, changes in sleep patterns and mood changes may occur. These effects will disappear in time.
- You may also experience vivid dreams and broken sleep for some weeks after withdrawal.
- 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 the self, that the mind is separated from body), 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. These symptoms may also be experienced between doses, especially if the dose is high.
- If you have been taking more than you should you may also experience confusion, convulsions or unusual behaviour. Do not stop taking your medicine without telling your doctor as he may wish to gradually reduce the number of tablets you take before stopping them completely.

4. Possible side effects

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

Stop treatment and contact a doctor immediately 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.

Contact your doctor if you develop:
- sore throats, infections, bruising or nose bleeds as these may be signs of changes in the number and types of blood cells. Your doctor may wish to give you a blood test.
- jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems).
- incontinence

- inability to urinate
- behavioural mood changes such as aggressiveness, delusions (false beliefs), rage, depression and psychoses.

Tell your doctor or pharmacist if any of the following side effects occur or if you notice any other effects not listed:
Common - drowsiness the following day • numbed emotions • reduced alertness • dizziness • confusion • fatigue • tiredness • shaky movements • double vision • co-ordination disturbances • muscle weakness • lightheadedness • memory loss • respiratory depression • slurred speech.

Rare - vivid dreams • restless sleep • awareness of abnormal heartbeat • skin reactions • changes in sex drive • sedation • impaired muscular functions • dry mouth • stomach upsets (indigestion, diarrhoea, constipation) • changes in the blood (identified by blood tests) • reduced urine output • visual disturbances • headache • 'spinning' sensation • low blood pressure • salivation changes • difficulty in speaking • shaking.

Other behavioural mood changes such as restlessness, agitation, irritability, nightmares, hallucinations, sleepwalking have also been reported mainly in elderly patients. When these reactions occur, you should tell your doctor and stop taking Temazepam tablets. Psychological dependence may occur, meaning you think that you cannot ever sleep without taking Temazepam tablets.

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, 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 (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.

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

Store at or below 25°C in a dry place. Protect from light.

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 contains

- The active substance (the ingredient that makes the medicine work) is temazepam. Each tablet contains either 10mg or 20mg of the active ingredient.
- The other ingredients are lactose monohydrate, maize starch, pregelled starch, sodium starch glycollate, microcrystalline cellulose and magnesium stearate.

What Temazepam Tablets looks like and contents of the pack

Temazepam 10 mg tablets are round, white to pale yellow tablets with TEM 10 on one side and plain on the other.

Temazepam 20 mg tablets are round, white to pale yellow tablets with TEM 20 on one side and plain on the other.

They are supplied in plastic containers of 28, 30, 56, 60, 84, 100, 168, 200, 250 and 500 tablets. Not all pack sizes may be marketed.

Marketing authorization holder and Manufacturer

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