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 as a pre-medication before major surgery
- for the short-term treatment of anxiety (overactive mind, thinking)
- for the short-term treatment of depression
- for the short-term treatment of panic attacks
- to reduce the risk posed to yourself and others you must talk to your doctor immediately if this occurs

Other medicines and Temazepam tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:
- alcohol which may increase the sedative effects and make you very sleepy
- sedative antihistamines
- muscle relaxants (baclofen and tizanidine)
- medicines to treat depression or anxiety e.g. fluvoxamine
drug interactions
- medicines to treat epilepsy (e.g. hydantoins (e.g. phenytoin), barbiturates)
- medicines to treat severe mental illness e.g. chlorpromazine, clozapine
- strong painkillers e.g. morphine
- medicines for substitution therapy and some cough medicines
- medicines to treat respiratory diseases
- medicines which act on the brain causing sedation including:
  - medicines to treat severe mental illness (e.g. chlorpromazine, clozapine)
  - medicines to treat respiratory problems (e.g. opioids) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concurrent 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 concurrent treatment should be limited by your doctor. Please tell your doctor about all other medicines you are taking, and follow your doctor’s dose recommendation closely. It could be helpful to tell the pharmacist and refer to be aware of the signs and symptoms stated above. Contact your doctor when experiencing any of the following:
- medicines to treat depression or anxiety e.g. fluvoxamine
- medicines to make you sleep
- antidepressants
- sedative antihistamines
- muscle relaxants (baclofen and tizanidine)
- medicines which lower high blood pressure (in particular m In rasidone or alpha blockers)
- medicines to treat severe mental illness e.g. chlorpromazine, clozapine

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

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."
- if you have any further questions, ask your doctor or pharmacist:
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.

How to take Temazepam tablets
The recommended dose is:

Adults:
• Insomnia: 10-20mg before going to bed. Your doctor may increase this to 30-60mg. 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 an 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 disorders:
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:
• Depressions, nervousness, confusion, tension, headache, anxiety, dizziness, loss of concentration or appetite, tremors, feeling or being sick, ringing in the ears, stomach cramps, heart or blood pressure disturbances, sleeplessness, irritability, sweating and diarrhoea, drowsiness resulting in feeling of unreality to the world around, depersonalisation (feeling of unreality to the self), that the mind is separated from body), hallucinations, painful sensitivity to sound, loss of feeling and tingling of the hands and feet, hyperirritability to light, noise and physical contact, muscle pain and restlessness.

• You may also experience vivid dreams and broken sleep for some weeks after withdrawal.

• 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.

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

Possible side effects
Like all medicines, this medicine can cause side effects, particularly when you first start taking it, although not everybody gets them.

Step treatment and contact a doctor 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, numbness, reduced alertness, confusion, impaired muscle coordination especially in the elderly, fatigue, headache, dizziness, muscle weakness, lack of co-ordination, double vision, (disturbed) shallow breathing (respiratory depression), slammed speech or breathing difficulties.

• Psychological effects:
restlessness, agitation, irritability, aggressiveness, delusions, rage, 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:
vomiting, stomach upset, changes in sexual desire, skin rash, difficulty passing water, weakness of mouth, tremor, loss of bladder control, light problems, increase in the amount of saliva, low blood pressure, muscle weakness, difficulty speaking, palpitations, Jaundice (yellowing of the skin or eyes), sore throat, itching of skin, or nose bleed 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.yellowcard.gov.uk 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.

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 dispose of any unused medicines you no longer use. These measures will help protect the environment.

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, microcrystalline cellulose, magnesium stearate and colloidal silica.

What Temazepam tablets look like and contents of the pack:
Temazepam tablets are white or off-white uncoated tablets.

Pack size 28 tablets
Marketing Authorisation Holder
Accord, Barnstaple, EX32 8NS, UK.

Manufacturer
Sunpharm-Services Limited, Unit 2H, Bre tty Business Park, Ashley Road East, Brett y, Burton-on-Trent, DE15 6YZ, United Kingdom.

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If you would like a leaflet with larger text, please contact 01271 385257

Temazepam All Strengths Tablets PIL - UK

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Ori gination Date: 17/01/2020

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Colours

Non Printing Colours

1. Black

2. 1

3. 3

4. 4

5. 5

6. 6

FMD info

NA INST a card

Yes No

Details

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