

Temazepam 10mg/5ml Oral Solution

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.

The name of your medicine is Temazepam 10mg/5ml Oral Solution but it will be referred to as 'Temazepam' throughout this leaflet.

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 other information

1. What Temazepam is and what it is used for

This medicine contains the active substance temazepam, which belongs to a group of medicines called benzodiazepines. Temazepam can be used:

- ▶ to help you sleep and re-set your sleep patterns when you have been having difficulty sleeping
- ▶ as a medicine that you should take before you have an operation or a test.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Temazepam

Do not take Temazepam if:

- ▶ you are allergic to temazepam, to other benzodiazepines or any other ingredients of this medicine (listed in section 6). The signs of an allergic reaction can include a rash, itching, difficulty breathing or swallowing or swelling of the face, lips, throat or tongue
- ▶ you have sudden or severe breathing problems
- ▶ you have severe liver problems
- ▶ you have 'myasthenia gravis'. The signs of this may be long term tiredness (fatigue) and muscle weakness
- ▶ you suffer from a condition where you stop breathing whilst asleep (sleep apnoea)
- ▶ you have an eye problem called "glaucoma"
- ▶ you have a severe mental health problem called "chronic psychosis" or a "phobic or obsessional state"
- ▶ you have anxiety problems with or without depression. Temazepam may cause you to think about killing yourself (suicide) more often
- ▶ you are breast-feeding.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking temazepam.

Warning and precaution

Talk to your doctor or pharmacist before taking temazepam if:

- ▶ you have any long-term kidney or liver problems
- ▶ you have or have ever had a history of alcohol or drug abuse (see "Dependence" below)
- ▶ you have a personality disorder such as schizophrenia
- ▶ you have recently suffered a loss or bereavement as the medicine may affect the way you react and adjust to this
- ▶ 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 temazepam
- ▶ you have a history of breathing problems. Whilst taking temazepam your breathing may become less forceful
- ▶ you suffer from or have history of depression
- ▶ you suffer from muscle weakness
- ▶ you are or suspect that you are pregnant.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking temazepam.

Other considerations:

Tolerance - if after a few weeks you notice that temazepam is not working as well as it 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. Temazepam can be habit forming. This medicine should only be used for the shortest time possible.

Withdrawal - treatment should be gradually withdrawn.

Withdrawal symptoms occur with temazepam even when normal doses are given for short periods of time. (See section 3 "If you stop taking Temazepam").

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.

Psychiatric and "paradoxical" reactions - Temazepam can cause behavioural side effects such as restlessness, agitation, irritability, aggressiveness, delusions (false beliefs), rage, nightmares, hallucinations, psychoses, sleepwalking, inappropriate behaviour, increased insomnia and other adverse behavioural effects.

Minor surgery - if you have been given temazepam 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines bought without a prescription, including herbal medicines. This is because Temazepam can affect the way some other medicines work. Also, some medicines can affect the way Temazepam works.

Do not take temazepam in combination with:

- ▶ Sodium oxybate, used to treat narcolepsy with cataplexy - sleep disorders with sudden or transient loss of muscle tone. Temazepam increases the effect of Sodium oxybate.

Take care when taking temazepam in combination with:

- ▶ medicines to treat severe mental illness such as chlorpromazine, olanzapine or schizophrenia such as clozapine
- ▶ medicines used for depression or anxiety including amitriptyline, fluoxetine, fluvoxamine and Monoamine Oxidase Inhibitors (MAOIs) such as phenelzine or other tranquillisers
- ▶ medicines that calm your emotions or help you sleep such as diazepam and zolpidem
- ▶ narcotic painkillers such as codeine and morphine or other painkillers
- ▶ lofexidine, used to treat drug problems (dependence)
- ▶ disulfiram, used for alcohol problems (alcoholism)
- ▶ medicines used to treat epilepsy such as phenytoin, barbiturates, hydantoin, carbamazepine or sodium valproate
- ▶ anaesthetics (used during surgery)
- ▶ antihistamines used to treat allergies that make you drowsy, such as chlorphenamine
- ▶ theophylline, used to treat asthma
- ▶ medicines used to treat high blood pressure such as moxonidine or doxazosin
- ▶ medicines used to treat HIV infection such as zidovudine and ritonavir
- ▶ medicines used to treat Parkinsons disease such as levodopa
- ▶ medicines that help the muscles relax in multiple sclerosis or spine injuries such as baclofen or tizanidine
- ▶ nabilone, used to treat sickness caused by chemotherapy
- ▶ cimetidine, used to treat stomach ulcers
- ▶ rifampicin, used to treat bacterial infections.

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 whilst taking this medicine. This medicine can make you sleepy and drinking alcohol when you are taking this medicine can make you even more sleepy.

Pregnancy and Breast-feeding

- ▶ 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.
- ▶ if your doctor has decided that you should take this medicine during late pregnancy or during labour, your baby may have a low body temperature, floppiness (hypotonia) and breathing or feeding difficulties
- ▶ if this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms.

Driving and using machines

Temazepam 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. This 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 contains:

Sorbitol (E420): This medicine contains 905mg sorbitol in each 5ml dose, which is equivalent to 181mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Ethanol (alcohol): This medicine contains 400 mg of alcohol (ethanol) in each 5ml dose, which is equivalent to 80mg/ml. The amount in 5ml of this medicine is equivalent to 10 ml beer or 4 ml wine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

The alcohol in this medicine may alter the effects of other medicines.

Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

Propylene glycol (E1520): This medicine contains 225mg propylene glycol in each 5ml dose, which is equivalent to 45mg/ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

Glycerol (E422): May cause headache, stomach upset and diarrhea.

3. How to take Temazepam

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

The recommended dose is:

Adults

For sleeping problems:

- ▶ the usual dose is 5ml to 20ml each day before going to bed
- ▶ this should only be taken for up to 4 weeks at a time
- ▶ your doctor may advise you to take this only when necessary.

As a pre-medication:

- ▶ the usual dose is 10 to 20ml, half to one hour before your surgery or test
- ▶ make sure that you have someone to take you home after the procedure.

Older people and people with disease of the blood vessels

- ▶ the usual dose is 2.5ml to 7.5ml
- ▶ take this each day before going to bed.

Use in children and adolescents

For sleeping problems:

- ▶ this medicine should not be used to help children sleep.

As a pre-medication:

- ▶ the usual dose is 0.5ml per kilogram of body weight before surgery or test
- ▶ the doctor will work out the correct dose for your child.

Method of administration

This medicinal product must be taken orally.

Long term use of this medicine is not recommended.

Use the measuring syringe provided in the pack to deliver the required dose.

Instructions for the use of syringe:

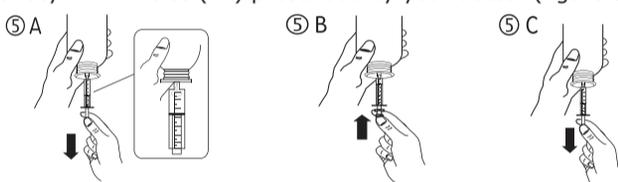
- a) Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).



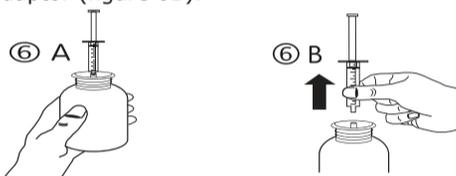
- b) Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



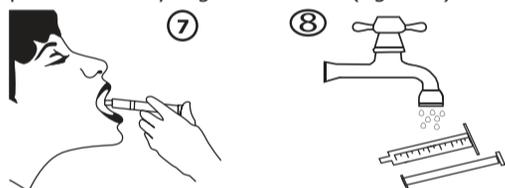
- c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



- d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Leave the syringe adaptor in place after first use. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you take more Temazepam than you should

If you take more of this medicine than you should, talk to a doctor or go to your nearest hospital straight away. Do not go unaccompanied to seek medical help. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you take too much the following effects may happen:

- ▶ having trouble with your co-ordination or muscle tension
- ▶ slurred speech
- ▶ feeling confused
- ▶ feeling tired, light-headed and possibly fainting (all due to low blood pressure)
- ▶ breathing problems
- ▶ falling into a coma.

If you forget to take Temazepam

- ▶ if you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose
- ▶ do not take a double dose to make up for a forgotten dose.

If you stop taking Temazepam

Do not stop taking this medicine unless your doctor tells you to. Do not stop it abruptly.

If the medicine is stopped quickly, the following effects may happen:

- ▶ feeling nervous, irritable, confused, being unable to sleep, finding it hard to concentrate
- ▶ feeling depressed, loss of appetite, having a headache, ringing in your ears (tinnitus), feeling dizzy, feeling detached from yourself or your surroundings (toxic psychosis)
- ▶ tingling hands or feet, sweating, being more sensitive to light, noise or touch than usual, fits and shaking, heart or blood pressure disturbances
- ▶ feeling or being sick, stomach cramps and diarrhoea.

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

4. Possible side effects

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

Stop taking this medicine and see a doctor **straight away** if you have any of the following:

▶ an allergic reaction.

The signs of an allergic reaction may include:

- swelling of your face, lips, tongue or throat or difficulty breathing or swallowing
- severe itching of your skin with raised lumps.

▶ A rare reaction that affects behaviour (may affect up to 1 in 1000 people)

The signs of this may include:

- feeling depressed and suicidal
- feeling excited, restless, agitated, irritable and confused

- aggressive outbursts or rages
- nightmares
- hallucinations (seeing or hearing things that are not there)
- delusions (thinking things are true that are not really true)
- feeling detached from yourself or your surroundings (psychosis)
- inappropriate behaviour
- sleepwalking (mainly in the elderly patients).

Tell your doctor if you get any of these side effects:

Common (may affect up to 1 in 10 people):

- ▶ feeling drowsy, sleepy, extremely tired or unable to sleep
- ▶ double vision
- ▶ feeling unsteady or dizzy
- ▶ feeling less alert to your surroundings
- ▶ numbed emotions
- ▶ lack of co-ordination or muscle weakness
- ▶ slurred speech
- ▶ shallow breathing
- ▶ memory loss
- ▶ light headedness
- ▶ confusion
- ▶ fatigue.

These side effects are more likely to occur at the start of treatment, if alcohol is taken with this medicine or if you are an older person.

Rare (may affect up to 1 in 1000 people):

- ▶ low blood pressure
- ▶ stomach upset (indigestion, diarrhoea, constipations)
- ▶ change in sexual desire
- ▶ headache
- ▶ jaundice (yellowing of the skin and whites of the eyes)
- ▶ difficulty passing water, reduce urine output
- ▶ skin reactions
- ▶ sight problems
- ▶ hangover
- ▶ shaking
- ▶ feeling dizzy or like you are spinning (vertigo)
- ▶ difficulty pronouncing your words, dry mouth or making more saliva than usual
- ▶ loss of control of your bladder or bowels (incontinence)
- ▶ impaired muscular function
- ▶ vivid dreams
- ▶ palpitations (abnormal heart beat)
- ▶ sedation.

You may have changes to your blood cells. The signs you may notice of this are feeling weak, sore throat, unexplained bruises or bleeding, getting more infections and sores or ulcers in your mouth.

You may develop tolerance to the effects of temazepam. This means you may notice that your medicine is not working as well to relieve your symptoms. If this happens, speak to your doctor.

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.

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 Website: 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 this medicine out of the sight and reach of children.
- ▶ Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.
- ▶ Discard 90 days after first opening.
- ▶ Keep the container in the outer carton in order to protect from light.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ 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 contains

The active substance is temazepam.

Each 5 ml of oral solution contains 10 mg of temazepam.

The other ingredients are ethanol (alcohol), propylene glycol (E1520), trometamol, citric acid monohydrate, liquid sorbitol (non-crystallising) (E420), purified water, peppermint oil, patent blue V (E131), caramel (E150) and glycerol (E422).

What Temazepam looks like and contents of the pack

Temazepam is a clear green colour solution with an odour of peppermint supplied in an amber glass bottle with tamper-evident, child resistant plastic cap and a 10ml oral syringe with graduation marks of 0.5ml for measuring and administering the dose.

Temazepam oral solution is supplied in a bottle containing 300ml solution.

Marketing Authorisation Holder:

SyriMed,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 ONU, UK

Manufacturer:

Delpharm Bladel B.V.
Industrieweg 1,
5531 AD Bladel,
Netherlands

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

MT: Temazepam Thame 10mg/5ml Oral Solution

UK (NI): Temazepam 10mg/5ml Oral Solution

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

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