SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Temazepam 10 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg of Temazepam.

Excipient(s) with known effect

Each tablet contains approximately 127.10 mg Lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

White to pale yellow, round, uncoated tablet debossed with TE above the score line and 1 below the score line and plain on the other side. Approximately 8 mm diameter.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Temazepam tablets are indicated for the short term treatment of insomnia, only where the condition is severe, disabling or subjecting the individual to extreme distress.

Temazepam tablets are indicated for pre-medication before minor surgery or other procedures especially in the case of outpatients.

4.2 Posology and method of administration

Route of administration: oral

Treatment to be given

- under close medical supervision
- at the lowest effective dose
- for the shortest possible duration (not exceeding 4 weeks).

Treatment should be tapered off gradually (see section 4.4).

Extension of use should not take place without further clinical evaluation.

Chronic use not recommended (little is known of the long term safety and efficacy: potential for dependence - see section 4.4).

When treatment is started the patient should be informed that

- treatment will be of limited duration
- the dosage will be progressively decreased
- there is the possibility of rebound phenomena.

Treatment should be initiated with the lowest recommended dose. Never exceed the maximum dose. Reduced doses may be suitable for patients who have cerebral vascular changes (e.g. arteriosclerosis) or impaired liver function.

Insomnia

These tablets should be taken on retiring or up to 30 minutes before going to bed.

Adults: 10-20 mg daily. In exceptional circumstances, the dose may be increased to 30-40 mg daily.

Children: The safety and efficacy of Temazepam in children less than 18 years of age has not been established and as such is not recommended for use.

The Elderly: 10 mg daily. In exceptional circumstances, the dose may be increased to 20 mg.

Pre-medication

Adults: The usual dose is 20-40 mg. This should be taken 30 to 60 minutes before surgery.

Children: The safety and efficacy of Temazepam in children less than 18 years of age has not been established and as such is not recommended for use.

The Elderly: Lower doses may be required by elderly patients, up to half the normal adult dose may be adequate.

Patients should be accompanied home when Temazepam has been used as a pre-medicant prior to surgery or other procedures on a day attendance basis.

4.3 Contraindications

Temazepam is contra-indicated in the following:

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Acute pulmonary insufficiency and where there is respiratory insufficiency
- Patients who have previously shown a hypersensitivity to benzodiazepines
- Obsessional states (inadequate evidence of safety and efficacy)
- Severe hepatic insufficiency (may precipitate encephalopathy)
- Neuromuscular respiratory weakness including myasthenia gravis
- Sleep apnoea syndrome (risk of further respiratory depression)
- Children
- Breastfeeding
- Planning a pregnancy (see section 4.6)
- Pregnancy (unless there are compelling reasons – see section 4.6).

Temazepam should not be used alone in depression or anxiety with depression (may precipitate suicide).

4.4 Special warnings and precautions for use

The cause for insomnia should be determined prior to the use of temazepam, and it should not be used for first line treatment of psychotic illness.

When temazepam is used for pre-medication, patients should be accompanied home afterwards.

Tolerance

Loss of efficacy to the hypnotic effects may develop after repeated use for a few weeks (chronic use not recommended-see section 4.2 for duration of therapy).

Dependence

The risk of dependence (physical or psychological) increases with dose and duration of treatment and is greater in patients with a history of alcohol or drug abuse, or in patients with a marked personality disorder. Therefore

- regular monitoring of such patients is essential
- routine repeat prescriptions should be avoided
- treatment should be withdrawn gradually.

Withdrawal effects

The duration of treatment should be as short as possible (see section 4.2)

If physical dependence has developed, abrupt termination of treatment results in withdrawal symptoms. These include headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability, sleep disturbance, diarrhoea and mood change. In severe cases the following may occur, a feeling of unreality or of being separated from the body, depersonalisation, confusional states, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, psychotic manifestations including hallucinations or epileptic seizures. Withdrawal symptoms will be worse in patients who have been dependent on alcohol or other narcotic drugs in the past, but can occur following abrupt cessation of treatment in patients receiving normal therapeutic doses for a short period of time.

Rebound symptoms

Symptoms including insomnia and anxiety may occur on withdrawal of treatment. As this is greater after abrupt discontinuation, the dose should be decreased gradually (see section 4.2).

Amnesia

Anterograde amnesia may also occur, most often several hours after ingestion. To reduce the risk, patients should ensure that they will be able to have an uninterrupted sleep of 7-8 hours (see also section 4.8).

Insufficient sleep may adversely affect the ability to drive/operate machinery etc (see section 4.7).

Bereavement/loss

Psychological adjustment may be inhibited by benzodiazepines.

Falls – particularly in the elderly

Due to muscle relaxant effects, benzodiazepines increase the risk of falls (and consequently hip fractures etc) particularly in the elderly when the get up at night (See section 4.2 – reduced dosage elderly patients).

Psychiatric and 'paradoxical reactions'

Reactions such as restlessness, agitation, irritability, aggressiveness, excitement, confusion, delusions, rages, nightmares, hallucinations, psychoses, inappropriate behaviour and other adverse behavioural effects can occur. These reactions are more likely to occur in children and the elderly, and extreme caution should be used in prescribing benzodiazepines to patients with personality disorders. Should they occur, treatment should be discontinued.

Risk from concomitant use of opioids:

Concomitant use of Temazepam and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related drugs such as Temazepam with opioids should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe Temazepam concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible (see also general dose recommendation in section 4.2).

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers (where applicable) to be aware of these symptoms (see section 4.5).

Specific Patients Groups

Patients with depression

Temazepam should not be used alone to treat depression or anxiety associated with depression as suicide may be precipitated in such patients.

Patients with a history of alcohol & drug abuse

Temazepam should be used with extreme caution in patients with a history of alcohol or drug abuse (risk of abuse/ dependence).

Patients with phobias and/or chronic psychoses

Temazepam is not recommended (inadequate evidence of efficacy and safety).

Pregnant women

Avoid regular use in pregnant women (risk of neonatal withdrawal symptoms); use only if clear indication such as seizure control (high doses during late pregnancy or labour may cause neonatal hypothermia, hypotonia and respiratory depression) (see also section 4.6).

Excipients:

Lactose: Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Not recommended

Alcohol: Temazepam should not be used together with alcohol (enhanced sedative effects: effect the ability to drive or operate machinery).

Sodium oxybate: Avoid concomitant use (enhanced effects of sodium oxybate).

To be taken into account

Centrally acting drugs: Combination with CNS depressants may enhance the central depressive effect during concomitant use of antipsychotics (neuroleptics), tranquillisers, hypnotics, anxiolytics/sedatives, antidepressants, narcotic analgesics, barbiturates, antiepileptic drugs, anaesthetics, sedative antihistamines and monoamine oxidase inhibitors. The elderly may require special supervision.

Antiepileptic drugs: Plasma phenytoin concentrations increased or decreased by temazepam, Phenytoin levels may need monitoring during temazepam withdrawal. Side effects may be more evident with hydantoins or barbiturates.

Narcotic analgesics: Enhancement of the euphoria may also occur, leading to an increase in psychological dependence.

Other drugs enhancing the sedative effect of Temazepam: Cisapride, lofexidine, Nabilone.

Compound that affect hepatic enzymes (particularly cytochrome P450):

- inhibitors (eg cimetidine; ritonavir; fluvoxamine) reduce clearance and may potentiate the action of benzodiazepines
- inducers (eg rifampicin) may increase clearance of benzodiazepines

Antihypertensives, vasodilators & diuretics: Enhanced hypotensive effects with ACEinhibitors, alpha-blockers, angiotensin-II receptor antagonists, calcium channel blockers adrenergic neurone blockers, beta-blockers, moxonidine, nitrates, hydralazine, minoxidil, sodium nitroprusside and diuretics. Enhances sedative effect with alpha blockers or moxonidine.

Dopaminergics: Concurrent use with benzodiazepines may decrease the therapeutic effects of levodopa.

Theophylline: Possible reduced effects of temazepam.

Antivirals: Concurrent use of zidovudine with benzodiazepines may decrease Zidovudine clearance.

Clozapine: Reports of cardiorespiratory collapse. Also increase in hypersalivation with both drugs.

Disulfiram: Inhibits the metabolism of benzodiazepines and enhances sedative effect. May cause temazepam toxicity.

Muscle relaxants (e.g. baclofen and tizanidine): Enhanced sedative effect.

Opioids:

The concomitant use of sedative medicines such as benzodiazepines or related drugs such as Temazepam with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dosage and duration of concomitant use should be limited (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

Temazepam should only be used during pregnancy if there are compelling reasons (e.g. no alternative: benefit outweighs risk).

An increased risk of congenital malformations in humans has been associated with benzodiazepine use, particularly if taken in the first and second trimesters. If the product is prescribed to a woman of childbearing potential, she should be warned to

contact her physician regarding stopping if she intends to become or suspects she may be pregnant.

If the product is administered at high doses during the late phase of pregnancy or during labour, effects on the neonate such as hypothermia, irregularities in foetal heart rate and hypotonia, poor sucking and moderate respiratory depression, can be expected. Infants born to mothers who took benzodiazepines chronically during the latter stages of pregnancy may have physical dependence and may be at some risk for withdrawal symptoms in the postnatal period.

Lactation

Use during lactation should be avoided as temazepam is found in breast milk.

4.7 Effects on ability to drive and use machines

Patients should be advised that sedation, drowsiness, amnesia, impaired concentration, dizziness, blurred vision and impaired muscle function may occur and that, if affected, they should not drive or use machines, or take part in other activities where this would put themselves or others at risk. If insufficient sleep duration occurs, the likelihood of impaired alertness may be increased. Concurrent medication may increase these effects (see also section 4.5).

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you
- It is an offence to drive while under the influence of this medicine

However, you would not be committing an offence (called 'statutory defence') 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 and in the information provided with the medicine and
- It was not affecting your ability to drive safely.

4.8 Undesirable effects

The following phenomena occur predominantly at the start of therapy and usually disappear thereafter:-

Drowsiness during the day, drowsiness and light-headedness the next day, numbed emotions, reduced alertness, confusion and ataxia (especially in the elderly), fatigue, dizziness, muscle weakness, and double vision.

More rarely, headache, vertigo, hypotension, salivation changes, visual disturbances, dysarthria, tremor, incontinence, urinary retention, blood disorders, jaundice, vivid dreams/nightmares, restless sleep, palpitations, change in libido, skin reactions, sedation, impaired muscular function, dry mouth and gastrointestinal disturbances may occur.

Pre-existing depression may be unmasked during benzodizapine use.

Blood dyscrasias and increased liver enzymes have also been reported to occur occasionally. If any of these effects do occur, treatment should be discontinued.

Rarely reported adverse reactions include hypersensitivity reactions.

Psychiatric and 'paradoxical' effects including paradoxical aggressiveness, restlessness, agitation, irritability, delusion, rages, nightmares, hallucinations, psychoses, excitement, confusion, and other changes in behaviour are known to occur when using benzodiazepines. Should this occur, use of the product should be discontinued. The reactions are more likely to occur in the elderly.

Anterograde amnesia may occur using therapeutic dosages, the risk increasing at higher dosages. Amnesia may be associated with inappropriate behaviour (see section 4.4).

Use (even at therapeutic doses) may lead to the development of physical dependence; discontinuation of therapy may result in withdrawal or rebound phenomena (see section 4.4). Psychological dependence may occur. Abuse has been reported in polydrug abusers.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Benzodiazepines potentiate the effects of other central nervous system depressants, including alcohol.

Features

Benzodiazepines commonly cause drowsiness, ataxia, dysarthria and nystagmus. Coma, hypotension and respiratory depression occasionally occur but are seldom serious if these drugs are taken alone. Coma usually lasts only a few hours but in elderly people it may be more protracted and cyclical. Respiratory depression is more serious in those with severe obstructive airways disease. Patients who are asymptomatic at 4 hours are unlikely to develop symptoms.

Management

- Maintain clear airway and adequate ventilation, if indicated.
- The value of gastric decontaminants is uncertain. Consider activated charcoal (50g for an adult: 1g/Kg for a child) within 1 hour of ingestion if more than 1mg/Kg has been taken provided the patient is not too drowsy.
- Gastric lavage – unnecessary if only benzodiazepine taken.
- Supportive measures as indicated by the patient's clinical condition.

Rarely flumazenil may used as an antidote, however it has a short half-life (about 1 hour). It should not be used in mixed overdoses or as a "diagnostic test".

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: hypnotics and sedatives, benzodiazepine derivatives, ATC code: N05C D07

Temazepam is a benzodiazepine; it has anxiolytic, sedative and hypnotic characteristics as well as possible muscle relaxant and anticonvulsant characteristics. Animal studies have shown anticonvulsant activity. These effects are most likely to be due to potentiation of gamma-aminobutyric acid (GABA), although other neurotransmitters may also be affected.

5.2 Pharmacokinetic properties

Absorption

Pharmacokinetic studies have shown that Temazepam is well absorbed from the gastrointestinal tract (90-100%, and the first pass effect is slight at about 5%). The time to reach peak plasma levels is usually about 50 minutes when administered orally. Maximum plasma levels observed after doses of 20mg are 660-1100ng/ml. With multiple dosing steady state is obtained by the third day and there is little or no accumulation of parent drug of metabolites.

Distribution

The volume of distribution is 1.3 to 1.5 l/kg body weight; for the unbound fraction 43-68 l/kg. Approximately 96% of the unchanged drug is bound to plasma proteins.

Metabolism

Temazepam is metabolised principally in the liver where most of the unchanged drug is directly conjugated to the glucuronide and excreted in the urine. Less than 5% of the drug is demethylated to oxazepam and eliminated as the glucuronide. The glucuronides of temazepam have no demonstrable CNS activity.

Elimination

Temazepam is rapidly eliminated, most studies showing an elimination half-life in the range 7-11 hours (mean 8 hours). Following a single dose, 80% of the dose appears in the urine, mostly as the conjugates and 12% of the dose appears in the faeces. Less than 2% of the dose is excreted unchanged in the urine.

Elimination in reduced renal function

In established renal insufficiency the metabolic clearance of temazepam as well as the plasma level of the non-protein bound temazepam remain within the normal range. The elimination half-life for temazepam glucuronide is however increased by which this inactive metabolite accumulates. As stated under 'overdose' it is unlikely that temazepam may be significantly removed by dialysis.

5.3 Preclinical safety data

Preclinical information has not been included because the safety profile of temazepam has been established after many years of clinical use. Please refer to section 4.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose,
Lactose Monohydrate,
Sodium starch glycolate,
Colloidal Anhydrous Silica,
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.

6.5 Nature and contents of container

PVC/PVdC/Aluminium foil blister packs, with blister packs contained in a carton together with the patient information leaflet.

Temazepam 10 mg tablets are sold in pack of 28,30, 50, and of 100 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

OSGEN PHARMACEUTICALS LIMITED
Unit 2 Cleveland Way, Hemel Hempstead Industrial Estate,
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United Kingdom

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PL 48836/0027

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