

Temazepam 10 mg, 20mg tablets

What is this medicine used for?

Temazepam is a sleeping aid and belongs to the group of benzodiazepines. Temazepam can be used in the treatment of sleep disorders. It promotes sleep if you have sleep disorders such as repeatedly waking up and/or difficulty falling asleep (again).

When should you be extra careful with this medication?

- If you have repeatedly used Temazepam for a few weeks, the sleep-inducing effect of Temazepam 10/20 mg tablets may decrease.
- If you are using or planning to use Temazepam, you should be aware that you may become psychologically and physically dependent on this medication. The risk of dependency is greater with higher prescribed doses and longer treatment duration. The risk is also higher in patients with a history of alcohol or drug abuse.
- Before starting treatment, your doctor will tell you how long you may use Temazepam. The treatment should be as short as possible. See also "How long can you use Temazepam?".
- Your doctor will inform you of the possible symptoms (the so-called "rebound" phenomenon) that may occur when you stop your treatment. See also "If you stop using this medication."
- If you have less than 7-8 hours to sleep, you should be aware that you may not remember what you experienced in the period after taking Temazepam.
- In children and elderly patients, more often reactions can occur that are completely opposite to the expected effect of Temazepam, such as restlessness, excitement, irritability, aggression, delusions, fits of anger, nightmares, certain mental disorders (psychoses), inappropriate and other oppositional behavior. If these reactions occur, treatment should be stopped.
- Temazepam is not a first-choice medication for the treatment of mental disorders. Temazepam should not be used as the sole treatment for depression or anxiety associated with depression.

Elderly patients: A lower dose is recommended for elderly patients (see "Dosage and method of use").

Patients with chronic respiratory disorders: If you have been suffering from respiratory disorders for a long time, a lower dose is recommended (see "Dosage and method of use").

Patients with liver disorders: If your liver function is impaired, your doctor may prescribe a lower dose in some cases (see "Dosage and method of use"). People who were previously mentally or physically dependent on alcohol or drugs. If you have had problems with alcohol or drugs in the past, your doctor will take the necessary extra precautions in consultation with you.

Are you using any other medications: If you are using other medications in addition to Temazepam, have done so recently, or may use other medications in the near future, tell your doctor or pharmacist.

When used concurrently with medications for mental disorders (antipsychotics), sleeping pills, tranquilizers and/or sedatives, medications for depression (antidepressants), opioids (certain strong pain relievers that are only available by prescription, addiction treatment drugs, and some cough medications), medications for epilepsy (antiepileptics), medications that provide general or local anesthesia (anesthetics), and medications used for allergies (antihistamines), the calming/sedative effect of Temazepam may be intensified. Concurrent use of opioids (very strong painkillers, some Means of treatment for addiction and some cough medicines can not only lead to drowsiness, but also difficulty breathing (respiratory depression) and coma, and life-threatening situations. Therefore, concurrent use should only be considered if no other treatment options are possible. If your doctor still prescribes Temazepam with an opioid, he or she should limit the dose and treatment duration. Concurrent use with opioids may result in an enhancement of the positive effect on mood. This can increase the mental dependence on these narcotic analgesics.

Tell your doctor about all opioid medicines you are taking and follow the prescribed dosage. It is also wise to inform friends or family members about the possibility of the above-mentioned symptoms occurring. Contact your doctor if such symptoms occur.

What to watch for with alcohol: The calming/sedative effect of Temazepam can be enhanced by the simultaneous use of alcoholic beverages.

Pregnancy and breastfeeding: Are you pregnant, think you are pregnant, want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

It is not clear whether the use of Temazepam during pregnancy is harmful to the unborn child. During the end of pregnancy, especially just before delivery, Temazepam should only be used in exceptional circumstances. Based on the properties of Temazepam, it is expected that the drug will have effects on the child, such as a decrease in body temperature, relaxation of muscles, and weakening of breathing.

Children of mothers who have used Temazepam for long periods during the last months of pregnancy may develop withdrawal symptoms after birth.

Benzodiazepines, the group of substances to which Temazepam belongs, are excreted in breast milk. Therefore, you should not use Temazepam if you are breastfeeding.

Driving and using machines: To drive a vehicle or operate a machine, you must be able to react and decide quickly and well. You must also be able to move quickly and precisely. If you use Temazepam, the control of these skills may be reduced because Temazepam can adversely affect attention, reaction time, memory, and the accuracy of muscle movements.

Temazepam contains lactose

If your doctor has told you that you are intolerant to certain sugars, contact your doctor before taking this medicine.

How to use this medicine?: Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist. When your doctor does not prescribe differently, use is as follows: Dosage and method of use.

The usual dosage for adults is: 10-20 mg per day. In exceptional cases, the doctor may increase the dosage to 30-40 mg per day.

The usual dosage for the elderly is: 10 mg per day. In exceptional cases, the doctor may increase the dosage to 20 mg per day.

Patients with liver or chronic respiratory disorders: Your doctor may lower the dosage in some cases compared to the usual adult dosage.

Strictly follow the number of Temazepam tablets per day and the treatment duration prescribed by your doctor. Follow your doctor's instructions, even if they differ from the above guidelines.

Time and method of intake: It is best to take the tablets with a large amount (half a glass) of water half an hour before going to bed. The score line is there to break the tablet if you have trouble swallowing the whole tablet.

How long can you use Temazepam?

Your doctor has taken into account your personal circumstances and needs when choosing the correct dosage. Generally, treatment lasts for a few days to two weeks. Including the tapering-off period, treatment should not last longer than four weeks. If you use Temazepam for more than 4 weeks, consult your doctor first. Do not use Temazepam for longer than the period indicated by your doctor!

Have you taken too much of this medicine?

If you use too much Temazepam at once, symptoms such as drowsiness, confusion, and lethargy may occur; in severe cases, ataxia (unsteadiness when walking), hypotonia (muscle relaxation), hypotension (lowering of blood pressure), weakened breathing, and sometimes coma.

If an overdose of Temazepam is suspected, a doctor should be notified as soon as possible.

Did you forget to take this medicine: Do not take a double dose to make up for a missed dose. If you forget a dose during your treatment, withdrawal symptoms may occur, especially if you are using a high dose (30-40 mg per day). See also "If you stop using this medicine."

If you stop using this medicine

If you suddenly stop treatment, you may experience one or more of the following withdrawal symptoms: headache, muscle pain, extreme anxiety, tension, restlessness, confusion, irritability, and mood swings. The symptoms for which you were prescribed Temazepam (insomnia) may also temporarily recur in increased severity. In more severe cases, withdrawal symptoms may include loss of sense of reality, alienation from oneself, numbness and tingling in the arms and legs, greatly increased sensitivity of the ear to sharp sounds (hyperacusis), hypersensitivity to light, sound, and touch, hallucinations, or epileptic seizures.

To minimize the risk of these symptoms occurring, it is recommended to gradually reduce the dosage and not stop treatment abruptly.

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N.B. Withdrawal symptoms mentioned earlier can also occur between doses of Temazepam, especially if you are using a high dosage. Consult your doctor about this!

Do you have any other questions about the use of this medication? Then please contact your doctor or pharmacist.

Possible side effects

Like any medication, this medication can have side effects, although not everyone experiences them.

- Especially during the first few days, you may experience one or more of the following symptoms: daytime sleepiness, blunted emotions, decreased alertness, confusion, fatigue, headache, dizziness, muscle weakness, ataxia (coordination disorder of the muscles usually manifested by uncertainty while walking), double vision. These side effects usually disappear by themselves with repeated use.
- Other side effects may include gastrointestinal disturbances, increased or decreased libido, and/or skin reactions.
- During treatment, it may become apparent that you do not remember what you experienced during the period after taking Temazepam. The possibility of these symptoms occurring increases with higher doses.
- Use of Temazepam may bring out a pre-existing but unnoticed depression.
- Use of Temazepam can cause unexpected reactions, such as restlessness, excitement, irritability, aggression, delusions, rage attacks, nightmares, certain mental disorders (psychoses), inappropriate and other oppositional behavior. These reactions occur more frequently in children and the elderly. See also "When should you be extra careful with this medication?".
- If you use or plan to use Temazepam, you should be aware that you can become dependent on this medication both mentally and physically. Withdrawal symptoms may occur when you suddenly stop treatment with Temazepam. See also "If you stop using this medication".

Reporting Side Effects

If you experience side effects, please contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly to the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medication.

How to store this medication?

- Keep out of sight and reach of children.
- Store below 25°C. Store in the original packaging to protect against moisture.
- Do not use this medication after the expiry date. This can be found on the box, label, and blister packs after "Exp". There is a month and a year. The last day of that month is the expiry date.
- Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications that you no longer use. They will be disposed of safely and the environment will be protected.