

PACKAGE LEAFLET

Package leaflet: Information for the user

Dalpam 2 mg tabletten
Dalpam 5 mg tabletten
Dalpam 10 mg tabletten

diazepam

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.

What is in this leaflet

1. What Dalpam is and what it is used for
2. What you need to know before you take Dalpam
3. How to take Dalpam
4. Possible side effects
5. How to store Dalpam
6. Contents of the pack and further information

1. What Dalpam is and what it is used for

Dalpam contain the active substance diazepam which belongs to a group of medicines called benzodiazepines. Dalpam has anxiolytic, sedative and muscle relaxant effect.

Dalpam is used:

- in the treatment of anxiety.
- in the treatment of muscle spasms, including those caused by cerebral spasticity (originates in the brain).
- for symptoms of alcohol withdrawal.
- to provide sedation before operations (premedication).

Your doctor may prescribe Dalpam for other uses. Please follow your doctor's instructions.

2. What you need to know before you take Dalpam

Do not take Dalpam

- if you are **allergic** to diazepam or any of the other ingredients of this medicine (listed in section 6).
- if you have a condition called **myasthenia gravis** which causes muscles to weaken and tire easily.
- if you suffer from **sleep apnoea** (a sleep disorder where you have abnormal pauses in breathing during sleep).
- if you have **severe liver** disorders.
- if you have **acute respiratory depression** (slow and/or shallow breathing).

Warnings and precautions

Talk to your doctor before taking Dalpam

- if you have a history of **alcoholism** or **drug abuse**.
- if you are **elderly**. Dalpam can cause confusion and have effects on muscles causing falls and injuries.
- if you have **breathing problems**.
- if you suffer from **depression**.
- if you have **suicidal thoughts**.
- if you have **epilepsy** or a history of **seizures**.

Other considerations

- **Mental side effects** – contact your doctor if you experience side effects such as agitation, hyperactivity, restlessness, aggressiveness, nightmares or hallucinations. These side effects are more likely to occur in children or the elderly.
- **Amnesia** – you could experience amnesia when taking this medicine. Amnesia is more likely to occur when taking high doses of diazepam.
- **Dependence** – when taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take Dalpam for as short period of time as possible.
- **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 speak to your doctor.
- **Withdrawal** – treatment should be gradually withdrawn. Withdrawal symptoms occur with Dalpam even when normal doses are given for short periods of time. See Section 3, ‘**If you stop taking Dalpam**’.

Children and adolescents

Do not give this medicine to children under the age of 6 years.

Other medicines and Dalpam

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Especially:

- cimetidine, omeprazole or esomeprazole (used to treat stomach ulcers and heartburn).
- medicines for epilepsy (antiepileptics),
- medicines to treat depression (antidepressants) or medicines to treat mental problems (antipsychotics),
- medicines used to treat allergies with a sedative effect (antihistamines),
- medicines to help you sleep (hypnotics) or to relieve anxiety (tranquilisers),
- some strong pain killers (analgesics such as morphine) and disulfiram (to treat alcohol addiction),
- rifampicin and isoniazid (antibiotics) and ketoconazole (anti-fungal),
- atazanavir and ritonavir (antiviral),
- propranolol (used to lower blood pressure),
- theophylline (to treat asthma).

Concomitant use of /.../ 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 /.../ 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.

Dalpam with food and drink and alcohol

Do not drink alcohol while you are taking diazepam. Alcohol may increase the sedative effects of Dalpam and make you very sleepy.

You should not drink **grape fruit juice** while taking diazepam as it causes diazepam to be removed from the body more slowly and increases the risk of side effects.

Pregnancy, breast-feeding and fertility

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.

You should not take Dalpam if you are pregnant, planning to become pregnant or are breast feeding. If you take Dalpam late in pregnancy or during labour your baby might have a low body temperature, floppiness and breathing difficulties. If taken regularly during late pregnancy, your baby may develop withdrawal symptoms.

Driving and using machines

Dalpam may make you feel sleepy and affect your concentration. It may also affect how your muscles work. These effects may continue for several days after discontinuation of treatment with diazepam.

Do not drive or use any tools or machines if you are affected in this way.

Dalpam contain lactose monohydrate

If you have been told that you have intolerance to some sugars contact your doctor before taking this medicine.

3. How to take Dalpam

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

Your doctor will decide the appropriate dose and for how long you need to take the tablets. The usual duration of treatment is no longer than 4 weeks. If needed, your doctor might increase the duration of treatment.

The recommended dose is:

Adults

For anxiety: 2 mg to 5 mg diazepam 2 to 3 times daily. The dose can be increased up to a maximum of 30 mg daily in 2 to 4 divided doses.

For treatment of muscle spasm: Up to 15 mg diazepam daily in 2 to 4 divided doses.

For treatment of muscle spasms in cerebral spasticity: Up to a maximum of 60 mg daily in 3 to 4 divided doses.

For treatment of alcohol withdrawal symptoms : 5 mg to 20 mg diazepam which may be repeated once after 2 to 4 hours if necessary, or 10 mg diazepam three to four times on the first day. After the first day, the dose is usually lowered to 5 mg diazepam three to four times daily as needed. In severe cases, your doctor may use other dosing schedules and treatment might need to take place in a hospital setting.

Premedication before operation: 5 mg to 20 mg diazepam once.

Use in children and adolescents

Children over 6 years of age (over 20kg)

The child's doctor will decide how much Dalpam should be given and how often. The usual dose is 0.1-0.3 mg/kg body weight daily in 2 to 4 divided doses.

Dalpam are not recommended for children below 6 years of age due to possible swallowing difficulties.

Swallow the tablets with a glass of water.

The tablet can be divided into equal doses.

Elderly patients

If you are elderly or frail you are likely to be more sensitive to the effects of Dalpam and your dose needs to be reduced. Your doctor will decide how much Dalpam you should be given and how often. Usual starting dose is 2 mg to 2.5 mg once or twice daily.

Impaired kidney function

Dose adjustment is usually not necessary.

Impaired liver function

If you suffer from cirrhosis or other liver problems your dose needs to be reduced.

Overweight patients

If you are overweight, it may take longer time for the medicine to work. Furthermore, the effects of Dalpam may take longer time to wear off including possible side effects.

If you take more Dalpam than you should

If you have taken too many tablets (more than prescribed), or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

Signs of an overdose include loss of coordination of muscle movements, sleep-like drowsy state, confusion, slurred speech and muscle weakness. An extreme overdose may lead to coma (unrousable unconsciousness), low body temperature (hypothermia), low blood pressure, slow pulse and severe breathing difficulties.

If you forget to take Dalpam

If you forget to take a dose take it as soon as you remember it. If you are about to take the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Dalpam

- Do not stop taking your medicine without talking to your doctor. You should gradually reduce the number or strength of tablets you take before stopping them completely.
- If you stop taking Dalpam suddenly, you may experience withdrawal symptoms including: anxiety, panic attack, palpitations (strong and pounding heartbeat), sweating, tremor, stomach problems, irritability, aggression, sensory disorder, muscle spasms, generally feeling unwell, loss of appetite, insomnia, mental side effects such as severe confusion and seizures. The likelihood and severity of withdrawal symptoms depends on the duration of treatment, dose strength and degree of dependency.
- If you have epilepsy or history of seizures and suddenly stop taking Dalpam there is a risk of convulsions or long-lasting epileptic seizure. There is also risk of seizures if you have an alcohol or drug abuse problem and suddenly stop taking Dalpam.

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

4. Possible side effects

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

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Some side effects can be serious and may require immediate medical treatment:

Uncommon: may affect up to 1 in 100 people

- Respiratory depression (very slow and/or shallow breathing)

Rare: may affect up to 1 in 1,000 people

- Respiratory arrest (cessation of breathing)
- Unconsciousness
- Jaundice (yellowing of your skin or the white of your eyes)

Very rare: may affect up to 1 in 10,000 people

- Anaphylaxis (severe allergic reaction) with symptoms such as sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow

Other side effects:

Very common: may affect more than 1 in 10 people

- Drowsiness

Common: may affect up to 1 in 10 people

- Fatigue
- Withdrawal symptoms (for possible symptoms please see '*If you stop taking Dalpam*' in Section 3)
- Confusion
- Loss of coordination of muscle movements (ataxia) and other movement disorders, tremor

Uncommon: may affect up to 1 in 100 people

- Muscle weakness
- Memory loss
- Difficulty in concentrating
- Balance disorders
- Dizziness
- Headache
- Slurred speech
- Stomach and intestinal problems such as nausea, vomiting, constipation, diarrhoea
- Increased salivation
- Allergic skin reactions in the form of itching, skin redness and swelling and skin rash

Rare: may affect up to 1 in 1,000 people

- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, memory loss, delusion, rages, psychoses, nightmares or hallucinations. May be or become serious. These side effects are more likely to occur in children or the elderly. Talk to your doctor.
- Decreased alertness
- Depression
- Emotional poverty
- Insomnia (problems sleeping)
- Heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest)
- Low blood pressure, fainting (syncope)
- Increased mucus in the lungs
- Dry mouth
- Increased appetite
- Changes in certain liver enzymes as seen in blood tests
- Lack of ability to urinate, loss of bladder control (leakage of urine)

- Enlargement of mammary glands in men
- Impotence, changes in sexual drive (libido)

Very rare: may affect up to 1 in 10,000 people

- Low levels of white blood cells (leukopenia)
- Higher level of a certain enzyme in the blood (transaminase)

Not known: frequency cannot be estimated from the available data

- Blurred vision, double vision and involuntary eye movements (these side effects disappear after you have stopped taking diazepam)

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 national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dalpam

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 label after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Dalpam contains

One tablet contains 2 mg/5 mg/10 mg diazepam

- The active substance is diazepam.
- The other ingredients are lactose monohydrate, pregelatinised maize starch and magnesium stearate.

What Dalpam looks like and contents of the pack

Diazepam 2 mg tablets: white to almost white round, flat, 8.0 mm in diameter, with "2" on one side and a break line on the other side.

Diazepam 5 mg tablets: Tablet is white to almost white round, flat, 8 mm in diameter, with "5" on one side and a break line on the other side.

Diazepam 10 mg tablets: Tablet is white to almost white round, flat, 8 mm in diameter, with "10" on one side and a break line on the other side.

Al/PVC blisters and HDPE tablet containers with white PE caps.

Al/PVC blisters

Pack sizes: 10, 20, 25, 28, 30, 50, 60 and 100 tablets

HDPE container

Pack size: 100, 500 and 1000 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Neogen NV
Square Marie Curie 50
1070 Anderlecht
België

Manufacturer(s)

SANTA SA
Str. Panselelor nr. 25, nr. 27, nr. 29
Brasov
jud. Brasov, cod 500419
Roemenië

In het register ingeschreven onder:

Dalpam 2 mg tabletten	RVG 118082
Dalpam 5 mg tabletten	RVG 118083
Dalpam 10 mg tabletten	RVG 118084

This medicinal product is authorised in the Member States of the EEA under the following names:

Kroatië:	Dalpam
Nederland:	Dalpam

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2023.