

## Package leaflet: Information for the user

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

### 1. What Diazepam STADA is and what it is used for

Diazepam STADA contains the active substance diazepam, which belongs to a group of medicines called benzodiazepines.

Diazepam STADA is used for the treatment of the following conditions:

#### In adults:

- symptoms of anxiety
- symptoms that occur during alcohol withdrawal

#### In adults and children over 6 years old:

- muscle spasms or pain caused by inflammation of muscles and joints or trauma, including spasms caused by conditions such as cerebral palsy (group of disorders that affect the ability to move, maintain balance and posture) and paraplegia (paralysis of the lower half of the body, affecting both legs) as well as athetosis (continuous, involuntary, slow movements and unusual fingers and hands) and stiff-person syndrome

### 2. What you need to know before you take Diazepam STADA

#### **DO NOT take Diazepam STADA if you**

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

### Warnings and precautions

Talk to your doctor or pharmacist before taking Diazepam STADA if you have

- liver, heart or kidney problems
- a history of alcoholism or drug abuse
- muscle weakness
- breathing problems
- mental problems. Benzodiazepines are not recommended as first-line treatment for psychosis (mental conditions). These medicines should not be used to treat depression or anxiety associated with depression as the symptoms may get worse
- epilepsy or a history of seizures

#### **Talk to your doctor if**

- after a few weeks you notice that the tablets are not working as well as they did when first starting treatment. Tolerance to benzodiazepines may occur
- you experience side effects or behavioural changes (see section 4)

There is a risk of dependence when taking this medicine.

#### **Children and adolescents**

**Do not give this medicine to children under the age of 6 years unless it is done after consultation with and under the strict medical supervision of a specialist (paediatrician, neurologist, psychiatrist, anaesthesiologist or critical care physician) who will determine the dose.**

Children have an increased sensitivity to the effects of benzodiazepines on the central nervous system, as their bodies are not fully developed to metabolise this medicine. This may lead to more of the active substance being present in their body.

#### **Other medicines and Diazepam STADA**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some other medicines may also change the way Diazepam STADA works. Especially:

- **antidepressants** (e.g. fluvoxamine, fluoxetine)
- **antipsychotics** such as clozapine (to treat mental problems)
- **muscle relaxants** (e.g. suxamethonium, tubocurarin)
- barbiturates such as **phenobarbital** (to treat epilepsy and mental disorders)
- other **central nervous system depressants** (buprenorphine, narcotic analgesics, opioids and derivatives used to treat coughs, baclofen, thalidomide, pizotifen, centrally acting antihypertensives)  
Taking these medicines with diazepam could affect your mental state, make you very sleepy and suppress your breathing and blood pressure
- **disulfiram** (to treat alcohol addiction). Taking this medicine with diazepam could make you very sleepy and can cause diazepam to be removed from the body more slowly than usual
- **medicines for epilepsy** e.g. phenytoin and carbamazepine, as these can reduce the effect of diazepam. Diazepam can furthermore affect how phenytoin works
- **theophylline** (to treat asthma and other breathing disorders), as it can weaken the effect of diazepam
- **cimetidine, omeprazole or esomeprazole** (stomach acid reducing medicines), as these can cause diazepam to be removed from the body more slowly than usual
- **rifampicin** (an antibiotic) as this can cause diazepam to be removed from the body more quickly than usual. The effect of diazepam can be weakened
- **atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir or saquinavir** (antivirals), **fluconazole, itraconazole, ketoconazole or voriconazole** (anti-fungal medicines) as these can cause diazepam to be removed from the body more slowly than usual and therefore increase the risk of side effects
- **isoniazid** (used to treat tuberculosis), as it can cause diazepam to be removed from the body more slowly than usual

- **oral contraceptives**, as they can slow down the removal of diazepam from the body and increase its effect. Breakthrough bleeding can occur when taking diazepam and oral contraceptives together, but the contraceptive protection is not reduced
- **cisapride** (used to treat stomach problems), as it can cause diazepam to be removed from the body more slowly than usual
- **corticosteroids** (medicines used to treat inflammation in the body) as they can weaken the effect of diazepam
- **levodopa** (used to treat Parkinson's disease). Diazepam can reduce the effect of levodopa
- **valproic acid** (used to treat epilepsy and mental disorders) as it can slow down the removal of diazepam from the body and increase its effect. Valproic acid taken with diazepam increases the risk of psychoses (mental conditions)
- **ketamine** (an anaesthetic) as diazepam increases the effect of ketamine

### **Opioids**

Simultaneous use of Diazepam STADA and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression) and coma, and may be life-threatening. Because of this, simultaneous use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Diazepam STADA together with opioids, the dose and duration of simultaneous 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.

### **Diazepam STADA with food, drink and alcohol**

**Do not drink alcohol** while you are taking diazepam. Alcohol may increase the sedative effects of Diazepam STADA.

Grapefruit juice might increase the effect of diazepam.

### **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 Diazepam STADA if you are pregnant, planning to become pregnant or are breast-feeding. This medicine might affect your baby.

### **Driving and using machines**

Ask your doctor before driving or using machines as Diazepam STADA may slow your reactions. These effects are increased by the use of alcohol and lack of sleep.

### **Diazepam STADA contains lactose**

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

## **3. How to take Diazepam STADA**

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

### **Dosage**

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.

### **Use in adults**

Recommended dose for:

- Anxiety symptoms
  - 2 mg to 5 mg diazepam 2 to 3 times dailyThe dose can be increased up to a maximum of 30 mg daily in 2 to 4 divided doses.
- Alcohol withdrawal syndrome
  - 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 dayAfter 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.
- Muscle spasms
  - up to 15 mg diazepam daily in 2 to 4 divided doses
- Muscle spasms in cerebral spasticity
  - up to a maximum of 60 mg daily in 3 to 4 divided doses

### **Use in children and adolescents**

#### Children over 6 years old and adolescents (over 20 kg)

The child's doctor will decide how much Diazepam STADA 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.

#### Children below 6 years old

Diazepam STADA is not recommended for children below 6 years of age due to possible swallowing difficulties. More suitable pharmaceutical forms may be available for younger children.

Do not give this medicine to children under the age of 6 years unless it is done after consultation with and under the strict medical supervision of a specialist (paediatrician, neurologist, psychiatrist, anaesthesiologist or critical care physician) who will determine the dose.

### **Use in elderly**

Your doctor will decide how much Diazepam STADA you should be given and how often. The dose will be lower than the usual dose prescribed for other adults. Treatment should be initiated with the lowest possible dose (2 to 2.5 mg, once or twice a day) and increased gradually if necessary and tolerated.

### **Use in patients with kidney impairment**

Dose adjustment is usually not necessary. However, patients with kidney failure should be careful when taking diazepam.

Benzodiazepines with active metabolites such as diazepam should be avoided for patients with end-stage kidney disease.

### **Use in patients with liver impairment**

Your doctor will decide how much Diazepam STADA you should be given and how often. The dose will be lower than the usual dose prescribed for other adults.

Patients with severe liver disorders, must not be treated with Diazepam STADA (see also "DO NOT take Diazepam STADA if you").

### **Use in overweight patients**

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

### **Method of administration**

The tablet can be divided into equal doses.

### **If you take more Diazepam STADA 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 or pharmacist immediately
- signs of an overdose include loss of coordination of muscle movements, severe breathing difficulties (apnoea), low blood pressure (hypotension), heart and lung problems (cardiorespiratory depression) and coma (unarousable unconsciousness)

### **Duration of treatment**

The duration of treatment should be as short as possible. In general, the treatment should not exceed 8 to 12 weeks.

### **If you forget to take Diazepam STADA**

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. If you are about to take the next dose, skip the missed dose.

### **If you stop taking Diazepam STADA**

- do not stop taking your medicine without talking to your doctor. If you stop taking Diazepam STADA suddenly you may experience withdrawal symptoms, including sleep disorders, headache, muscle pain, tension, confusion, irritability or aggression, mood changes and hypersensitivity to light, noise and physical contact. Less common withdrawal symptoms are seeing or hearing things which are not there (hallucinations) and loss of perception of reality (derealisation)
- you should gradually reduce the number or strength of tablets you take before stopping them completely. Your doctor will tell you how

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.

### **Some side effects can be serious and may require immediate medical attention:**

#### Allergic reactions

If you develop an allergic reaction, you should **seek medical attention immediately**. The side effects are as follows:

- sudden swelling of your throat, face and lips which can lead to difficulties breathing and swallowing
- sudden swelling of the hand, feet and ankles, rash or itching

#### Behavioural effects

**Talk to your doctor** if you notice any of the following side effects:

- aggression, irritability, nervousness, agitation, anxiety, delusions, anger
- sleep problems, nightmares and vivid dreams

The doctor may ask you to stop the treatment.

For possible withdrawal symptoms please see “If you stop taking Diazepam STADA” in Section 3.

These are more likely to occur in children and the elderly.

#### Elderly patients

There is an increased risk of falls and associated fractures in elderly patients using benzodiazepines.

### **Other side effects:**

**At the beginning of the treatment with Diazepam STADA**, you may experience the following side effects:

- drowsiness, fatigue, dizziness and light-headedness
- muscle weakness, loss of coordination of muscle movements (ataxia) and other movement disorders

The doctor may propose a lower dose of Diazepam STADA and then slowly increase it.

**The following side effects might occur during the treatment:**

Psychiatric disorders and nervous system

- difficulty in concentrating, decreased alertness, confusion and disorientation, agitation
- memory loss
- headache
- depression
- slurred speech
- loss of coordination, including instability when walking
- changes in sexual drive (libido)

Liver and blood (very rare)

- changes in certain liver enzymes as seen in blood tests
- yellowing of the skin or eyes (jaundice)
- blood problems. The signs may include fatigue, easy bruising, shortness of breath and nosebleeds. Your doctor may ask you to take blood tests from time to time

Heart, circulation and blood vessels

- heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest)
- low blood pressure (hypotension). You might experience dizziness or light-headedness while standing
- circulation problems (circulatory depression)

Stomach and intestine (occasionally)

- nausea
- constipation
- stomach pain
- dry mouth and increased salivation

Lungs and kidneys

- respiratory depression
- lack of ability to urinate (urinary retention), loss of bladder control (leakage of urine)

Eyes, skin and hair

- double vision
- blurred vision
- vertigo with signs such as dizziness or spinning sensation
- the most common reactions are skin rash, hives, itching and rash erythematous

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 Diazepam STADA

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 protect the environment.

## 6. Contents of the pack and other information

### What Diazepam STADA contains

- The active substance is diazepam.  
Each tablet contains 2 mg of diazepam.  
Each tablet contains 5 mg of diazepam.  
Each tablet contains 10 mg of diazepam.
- The other ingredients are lactose monohydrate, pregelatinised maize starch and magnesium stearate.

### What Diazepam STADA looks like and contents of the pack

Tablet is white to almost white round, flat, 8.0 mm in diameter, with "2" on one side and break line on the other side.

Tablet is white to almost white round, flat, 8.0 mm in diameter, with "5" on one side and break line on the other side.

Tablet is white to almost white round, flat, 8.0 mm in diameter, with "10" on one side and break line on the other side.

The tablet can be divided into equal doses.

Diazepam STADA are packed in Al/PVC blisters. Blisters together with patient information leaflet are placed in a carton with imprinted label text.

Diazepam STADA are packed in Al/PVC blisters or white HDPE bottles with PE screw cap. Blisters together with patient information leaflet are placed in a carton with imprinted label text. Bottles either have booklet label leaflet or together with patient information leaflet are placed in a carton with imprinted label text.

Diazepam STADA are packed in Al/PVC blisters or white HDPE bottles with PE screw cap. Blisters together with patient information leaflet are placed in a carton with imprinted label text. Bottles either have booklet label leaflet or together with patient information leaflet are placed in a carton with imprinted label text.

### Pack sizes:

20, 20x1, 25, 25x1, 30, 30x1, 50, 50x1, 60,60x1, 90, 90x1, 100and 100x1 tablets in blisters.

20, 20x1, 25, 25x1, 30, 30x1, 40, 40X1, 50, 50x1, 60, 60x1, 90, 90x1, 100 and 100x1 tablets in blisters or 20 tablets in bottles.

20, 20x1, 25, 25x1, 30, 30x1, 50, 50x1, 60, 60x1, 90, 90x1, 100 and 100x1 tablets in blisters or 20 tablets in bottles.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Vergunning holder:**

STADA Arzneimittel AG  
Stadastr. 2 – 18  
61118 Bad Vilbel  
Duitsland

### **Fabrikant:**

SANTA S.A.  
Str. Panselelor nr. 25, nr. 27 si nr. 29  
Brasov, jud. Brasov, cod 500419  
Roemenië

STADA Arzneimittel AG  
Stadastr. 2 – 18  
61118 Bad Vilbel  
Duitsland

### **In het register ingeschreven onder**

Diazepam STADA 2 mg tabletten RVG 127016  
Diazepam STADA 5 mg tabletten RVG 127017  
Diazepam STADA 10 mg tabletten RVG 127018

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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

BE	Diazepam Eurogenerics 2 mg tabletten Diazepam Eurogenerics 5 mg tabletten Diazepam Eurogenerics 10 mg tabletten
CZ	Diazepam STADA
IT	Diazepam EG Stada
LU	Diazepam Eurogenerics 2 mg comprimés Diazepam Eurogenerics 5 mg comprimés Diazepam Eurogenerics 10 mg comprimés
NL	Diazepam STADA 2 mg tabletten Diazepam STADA 5 mg tabletten Diazepam STADA 10 mg tabletten
PL	Diazepam STADA

Deze bijsluiter is voor het laatst aangepast in april 2023