PATIENT INFORMATION LEAFLET

DİAPAM 10 mg/2 mL ampoule

For intramuscular and intravenous administration.

- ***Active Ingredient:*** Each 2 mL ampoule contains 10 mg diazepam.
- ***Excipients:*** Propylene glycol, ethyl alcohol, sodium benzoate, benzoic acid, benzyl alcohol and water for injection.

Read all of this leaflet carefully before you start using 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.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high or low doses** other than the recommended dosage.*

What is in this leaflet:

1. What DİAPAM is and what it is used for?

The active substance of DIAPAM is diazepam, which is included in a group of drugs called benzodiazepines. Each ampoule contains 10 mg of active substance in 2 ml.

DIAPAM is presented in carton boxes with 10, 50 or 100 ampoules of 2 ml, one patient information leaflet. DIAPAM is used in the treatment of the following conditions:

- In the short-term treatment of anxiety (worry, anxiety),
- Symptoms that occur in patients who quit alcohol (restlessness, tremor, delusions, anxiety-exuberance, delirium)
- Helping the muscles to relax and for muscle contractions and cerebral stroke (a condition that affects the brain and causes movement problems and muscle stiffness)

- Remittance (seizure)
- Shivering (may be familial, sometimes the cause may not be known)
- A progressive type of painful muscle contractions

2.What you need to know before you use DİAPAM

DO NOT USE DİAPAM;

If;

- You are allergic (hypersensitive) to diazepam or other benzodiazepine group drugs or any of the excipients in DİAPAM
- You are short of breath or have trouble breathing
- You are experiencing a mental breakdown (with or without anxiety)
- You have a mental illness (psychosis)
- You have narrow angle glaucoma (increased intraocular pressure)
- You have a disease called myasthenia gravis (a type of muscle weakness disease)
- There is temporary respiratory failure during sleep
- You have severe liver disease
- Porphyria (an inherited condition that causes blisters on the skin, abdominal pain, and nervous system diseases)
- DİAPAM is not used in babies younger than 6 months.

USE DİAPAM CAREFULLY if you;

Consult your doctor before using this medicine.

If;

- You have had alcoholism or substance abuse problems in the past
- You have severe kidney failure
- You have lung problems
- You have low levels of a protein called albumin in your blood
- You have a personality disorder
- If you are old (risk of confusion or inattention that could cause you to fall or injure)
- Stopping DİAPAM suddenly in patients with epilepsy may increase the frequency and severity of seizures.
- There is a risk of addiction while taking DİAPAM, and this risk increases with drug dosage and duration of treatment, as well as in patients who have experienced alcoholism and substance addiction.

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Use of DİAPAM with food and drink

DİAPAM does not interact with foods.

Do not take DİAPAM with alcohol. Alcohol can increase the sedative effects of DİAPAM and make you feel extremely drowsy.

Grapefruit juice can increase the amount of diazepam in the blood.

Drinks containing caffeine can reduce the effect of diazepam.

Pregnancy

Consult your doctor or pharmacist before using this medication.

The risk of congenital malformation (congenital structural disorders in organs and tissues) increases with its use in the first trimester of pregnancy. Therefore, the risk / benefit ratio should be carefully evaluated during pregnancy.

Do not use DİAPAM during pregnancy unless absolutely necessary.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

Since the active ingredient of DİAPAM passes into breast milk, women who are breastfeeding should avoid using this drug during this period.

If you are breastfeeding your baby, do not use DİAPAM.

Driving and using machines

Since DİAPAM may cause a decrease in attention and alertness, muscle functions, it can cause dangerous consequences for people who use vehicles and machines.

If you experience such an effect, do not use vehicles or machines.

Important information about some of the excipients in DİAPAM

- DİAPAM ampoules contain propylene glycol. Therefore, it can cause alcohol-like symptoms.
- This medicinal product contains 200 mg of ethanol (alcohol). It can be harmful for those with alcohol addiction.
- To be taken into account in pregnant or breastfeeding women, children and high risk groups such as patients with liver disease or epilepsy.
- This medicinal product contains less than 1 mmol (23 mg) sodium in 2 ml; that is, it is considered essentially free of sodium.
- DİAPAM contains 40 mg benzoic acid in 2 ml. Therefore, it may increase the risk of jaundice in newborn babies.

- DİAPAM contains 30 mg benzyl alcohol in 2 ml. It should not be administered to premature babies and newborns.
- May cause toxic reactions and allergic reactions in infants and children up to the age of 3.

Using other medicines

- Cimetidine (a drug used in the treatment of ulcers) or isoniazid (a drug used in the treatment of tuberculosis), as it slows the elimination of DİAPAM from the body.
- Rifampicin (a drug used in the treatment of infections) because it causes DİAPAM to be eliminated from the body faster
- Antacids (drugs that reduce stomach acidity) may slow the absorption of DİAPAM in the body.
- Carbamazepine may decrease serum levels of both drugs, reducing their effects.
- May interact with other central nervous system depressants. The effect is intensified. The use of these drugs together with DİAPAM may cause severe drowsiness.
- Concomitant use with neuromuscular junction blockers (curare-like drugs, muscle relaxants) may cause severe drowsiness.
- Using DİAPAM with alcohol can cause drowsiness.
- The risk of developing withdrawal syndrome increases with the combination of benzodiazepines prescribed as anxiolytics (anxiety, drugs used to prevent anxiety) or hypnotics (drowsiness drugs).
- Combined use with dopaminergic drugs (levodopa) used in the treatment of Parkinson's may reduce the effects of these drugs.
- Itraconazole, ketoconazole, and fluconazole can increase the effects of benzodiazepines. It may be necessary to reduce the benzodiazepine dose.
- Theophylline reduces the effect of diazepam.
- Grapefruit juice can prolong the effect of diazepam. Although this interaction is of little importance in healthy individuals, other factors such as aging or liver cirrhosis can increase the risk of side effects.

If you are currently using any prescription or non-prescription medicine or have used it recently, please inform your doctor or pharmacist about them.

3.How to use DİAPAM

Instructions for use and dose/administration frequency:

Your doctor will determine the dose of your medicine depending on your illness and administer it

to you.

For adults:

DİAPAM can be used in doses varying between 5-20 mg, depending on the type and severity of your disease and the decision of your doctor.

Method of administration:

DİAPAM is administered intravenously or intramuscularly.

Various age groups

Use in children:

- In tetanus:

1-2 mg is administered in children between the ages of 2-5. It should be given intravenously or intramuscularly over a 3-minute period. This dose can be repeated every 3-4 hours.

5-10 mg is administered in children older than 5 years. It should be given intravenously or intramuscularly over a 3-minute period. This dose can be repeated every 3-4 hours.

- In epilepsy and seizure:

0.2 - 0.3 mg / kg IV (or IM) or 1 mg per year of life.

Use in the elderly:

In elderly patients, it is recommended to use the lowest effective dose of DİAPAM, since the drug has effects on the central nervous system. If the drug is tolerable, the drug dose may be increased gradually.

Special cases of use:

Renal/Hepatic failure:

DİAPAM should be used with caution in patients with impaired renal function. Your doctor may want to lower your dose.

Do not use DİAPAM if you have serious liver problems.

If you have an impression that the effect of DİAPAM is too strong or too weak, talk to your doctor or pharmacist.

If you use more DİAPAM than you should

Overdose symptoms include loss of attention and coordination, feeling sleepy or deep sleep, speech problems, muscle weakness or a sense of excitement, slow heart rate, weakness of breathing, and extreme weakness. Extremely high doses can cause coma (loss of consciousness), reflex problems, and difficulty breathing.

Talk to a physician or pharmacist if you have used more DİAPAM than you should use.

If you forget to use DİAPAM

Do not take double doses to make up for forgotten doses.

If you forget to take your dose of your medicine, take the missed dose as soon as you remember and take the next dose at the time.

Effects that may occur when treatment with DİAPAM is terminated

- Symptoms such as convulsions (convulsions), tremors, abdominal and muscle cramps, vomiting and sweating can be seen in the sudden cessation of DİAPAM. Therefore, the medication should be reduced gradually in any long-term treatment.
- If you use high doses of medication, you may occasionally experience symptoms such as confusion, convulsions or unusual behavior.
- Stop the treatment gradually, otherwise your illness may recur more severely than before. This risk is higher when you stop your DİAPAM treatment suddenly. Mood changes, anxiety, restlessness, or changes in sleep patterns may be seen.

4. Possible side effects

As with all medicines, there may be side effects in people who are sensitive to the ingredients of DİAPAM.

The frequency of adverse events is reported using the following categories.

Very common	: can be seen at least 1 out of 10 patients.
Common	: can be seen less than one in 10 patients, but more than one in 100 patients.
Uncommon	: can be seen less than one in 100 patients, but more than one in 1,000 patients.
Rare	: can be seen less than one in 1.000 patients, but can be seen more than 10,000 patients in one.
Very rare	: can be seen less than one in 10,000 patients.
Unknown	: cannot be estimated from available data.

Common:

- Sleepiness, weakness, fatigue

Rare:

- Paradoxical reactions such as confusion (confusion), depression, difficulty falling asleep, excitation, irritability or irritability (hypersensitivity to stimuli, ability to react)
- Headache, dizziness, tongue wicking when speaking (dysarthria)
- Blurred vision or other visual (visual) changes
- Constipation (constipation), vomiting, nausea
- Jaundice

- Skin rashes and itching

Unknown

- Neutropenia, decreased number of fragmented cells in the blood

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5.How to store DİAPAM

Keep DİAPAM out of the reach and sight of children and within its packaging.

Store at room temperature under 25 ° C with protecting from light.

Use in compliance with the expiry date.

Do not use DİAPAM after the expiry date which is stated on the packaging.

If you notice any damage on the product and / or package, do not use DİAPAM.

Marketing Authorization Holder and Manufacturer:

Osel İlaç Sanayi ve Ticaret A.Ş.

Akbaba Mah. Maraş Cad. No: 52

Beykoz/ İSTANBUL

This patient information leaflet approved in ……..