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**PATIENT INFORMATION LEAFLET**

**CALCIOSEL 10% Ampoule Containing Solution for Injection**

**Sterile**

**It is administered intravenously and intramuscularly.**

- **Active substance:** Each ampoule contains 225 mg calcium gluconate monohydrate and 572 mg calcium levulinate dehydrate.
- **Excipient:** Water for injection.

**Read the PATIENT INFORMATION LEAFLET carefully as it includes vital 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.*
- *Please state that you are using this drug if you visit a physician or hospital during the administration of this drug.*
- *Please follow the instructions here precisely. Do not apply **higher or lower dose** other than the recommended.*

**In this Patient Information Leaflet:**

1. *What CALCIOSEL 10% is and what is it used for?*
2. *What you need to know before you apply CALCIOSEL 10%?*
3. *How to use CALCIOSEL 10 %*
4. *What are the possible side effects?*
5. *How to store CALCIOSEL 10 %*

**1. What is CALCIOSEL 10 %and what it is used for?**

- CALCIOSEL 10% is an ampoule included in the calcium active substance class within the mineral supplementation group.



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- CALCIOSEL 10% is a clear, colorless solution bottled in amber glass ampoules of 10 ml. Each box contains 5 ampoules.
- The use of CALCIOSEL 10% is as follows: hypoparathyroidism, fast growth or pregnancy- induced hypocalcemia, tetany due to calcium deficiency, auxiliary rickets (in children) and osteomalacia (in adults) treatment, prevention of acute colics observed in lead poisoning, magnesium sulfate poisoning, allergic conditions, non-thrombocytopenic purpura, exudative dermatoses, medicine-induced itching, prevention of hypocalcemia development in blood transfusion, fluoride poisoning, hypocalcemia, sudden cardiac arrest treatment, neonatal tetany.

**2. What you need to know before you apply CALCIOSEL 10%?**

If you are receiving drugs for cardiac disorder, inform your doctor.

**DO NOT APPLY CALCIOSEL 10% in the following cases**

If:

- You are hypersensitive to any of calcium gluconate monohydrate or calcium levulinate dehydrate,
- Severe renal failure,
- You are treated with the drugs ensuring stronger cardiac contraction,
- You have tachycardia,
- You have sarcoidosis,
- You have renal or cardiac disorder.

**APPLY CALCIOSEL 10% CAUTIOUSLY in the following cases**

If you are pregnant,

If these warnings apply to you even in any period in the past, please consult your doctor.

**Applying CALCIOSEL10% with food and drinks**

CALCIOSEL 10% does not have a known interaction with foods and drinks.

**Pregnancy**

*Consult your doctor or pharmacist before taking the drug*

Should not be taken during pregnancy unless necessary.



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*If you notice your pregnancy during the treatment, consult your doctor or pharmacist immediately.*

### **Lactation**

*Consult your doctor or pharmacist before taking the drug*

Calcium passes to the breast milk; therefore, care should be exercised when administering to lactating mothers.

### **Driving and using machines**

It has no adverse effect on driving and using machines.

### **Taking with other drugs**

CALCIOSEL 10% should not be used concomitantly with the drugs ensuring stronger cardiac contraction, such as digoxin.

Thiazide diuretics may increase the blood calcium level by reducing the urinary calcium excretion.

CALCIOSEL 10% may inactivate the tetracycline class antibiotics.

*If you are now taking or have taken recently any prescription or non-prescription drug, please inform your doctor or pharmacist about the drug.*

## **3. How to use CALCIOSEL 10%**

### **Instructions for appropriate use and dosing/administration frequency**

Your doctor will decide the dose and administer depending on your disease.

### **Route and method of administration**

CALCIOSEL 10% is administered intramuscularly and intravenously under doctor's control.

- Your doctor has prescribed a dose for you and stated the treatment period in your prescription.
- Do not change the dose by yourself.

### **Various age groups**

#### **Use in children:**

Your doctor will determine and administer the drug dose depending on your child's disease.



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**Use in geriatric population:**

Your doctor will decide the dose and administer depending on your disease.

**Specific conditions:**

If you have a severe renal disorder, you must inform your doctor. When administered to the patients with renal disorders, it should be followed up by the doctor.

Follow these instructions unless your doctor gives a different advice. Your doctor will tell you the duration of your treatment with CALCIOSEL 10%.

*If you believe that the effect of CALCIOSEL 10% is very strong or weak, consult your doctor or pharmacist.*

**If you take CALCIOSEL 10% more than you need to take**

*If you have taken CALCIOSEL 10% more than you need to take, consult a doctor or pharmacist.*

If you take CALCIOSEL 10% more than you need to take, your blood calcium levels will excessively increase, therefore the following symptoms may occur: loss of appetite, vomiting, constipation, stomach ache, muscle weakness, thirst, polyuria, numbness, confusion, demineralization-induced bone pain, nephrocalcinosis, high urinary volume due to the loss of renal concentration capacity, sometimes cardiac arrhythmia, comatose and cardiac arrest.

**If you forget to use CALCIOSEL 10%**

*Do not take double dose to compensate the missing doses.*

**Effects that may occur when CALCIOSEL 10% treatment is discontinued:**

No effect is expected.

**4. What are the possible side effects?**

As in all other drugs, side effects may appear in individuals who are sensitive to the substances contained in CALCIOSEL 10%.

**If any of the following cases occur, discontinue CALCIOSEL 10% use, IMMEDIATELY inform your physician and admit to the emergency service of the closest hospital:**

- Decreased blood pressure (tension) (symptoms: fatigue, weakness, tinnitus, dysmnnesia, impairment of concentration, cold hands and feet, dizziness, gray out)
- Increased or decreased heart rate, arrhythmias
- Presyncope

They are all very severe side effects.

If you have any of these, you have a severe level of allergy to CALCIOSEL 10%. You may need emergency medical intervention or hospitalization.

All of these severe side effects are very rare.

**If you notice any of the following conditions, inform your doctor immediately or refer to the emergency service of the closest hospital:**

- If the blood calcium level increases excessively (symptoms indicating the increased blood calcium level include loss of appetite, vomiting, constipation, stomach ache, muscle weakness, thirst, polyuria, numbness, confusion, demineralization-induced bone pain, nephrocalcinosis, cardiac arrhythmia).

They are all severe side effects. You may need emergency medical intervention. Severe side effects are observed very rarely.

**Inform your doctor if you notice any of the following conditions:**

- Hot flush and distress
- Chalk taste in mouth
- Pain, swells and bruises on the injection are.

These are the mild side effects of CALCIOSEL 10%.

*If you have any side effect which is not specified in the Patient Information Leaflet, inform your doctor or pharmacist about your condition.*

### **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.



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**5. How to store CALCIOSEL 10%**

*Keep CALCIOSEL 10 % in its package and out of sight and reach of children.*

Keep CALCIOSEL 10% at room temperatures below 25°C by protecting from light. Protect CALCIOSEL10% from freezing. When the product is mixed with 5% dextrose and 0.9% sodium chloride, it remains stable for 24 hours at 25 °C. If there is any crystallization inside the ampoule, it can be used after eliminating the crystallization by heating the ampoule up to 30-40°C before use. If crystallization is not eliminated or there are residues, do not use the ampoules.

Only use the clear, transparent ampoule solutions.

**Use in comply with the expiry date**

*Do not use CALCIOSEL 10 % after the expiration date which is stated on the package/use before the expiration date.*

If you notice any defect on product and/or package, do not take CALCIOSEL 10%.

***Marketing Authorization Holder:***

HAVER FARMA İlac A.S.

Acarlar Mah. 74. Sok. Acarkent Sitesi B742 No.:17/1

Beykoz / İstanbul /TURKEY

***Manufacturing Site:***

OSEL İlaç San. ve Tic. A.Ş.

Akbaba Mah. Maraş Cad. No.: 52

Beykoz / İstanbul/Turkey

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