PATIENT INFORMATION LEAFLET

TRİAVER ampoule 40 mg/ml, 1 ml

For intra-articular or intramuscular administration.

Active ingredient: Each 1 ml suspension contains 40 mg triamcinolone acetonide.

Excipients: Benzyl alcohol, polysorbate 80, sodium carboxy methyl cellulose, sodium chloride and water for injection

Read all of this PATIENT INFORMATION 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 medication is prescribed solely for you, do not offer it to others.*
- *If you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Follow the recommendations on this leaflet exactly as described. Do not use **higher or lower dose** except the dose you have been recommended for the medicine.*

In this Information Leaflet:

Headings are included.

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

TRİAVER is a white, whitish, and odorless or slightly benzyl alcohol scented fluid suspension and belongs to a group of drugs called corticosteroids. TRİAVER is offered for use with the packaging form containing 1 ampoule of 1 ml.

TRİAVER is used in the treatment of a wide range of serious inflammatory and / or allergic diseases such as endocrine diseases, rheumatic diseases, collagen tissue diseases, gastrointestinal system and lung problems, skin diseases, eye diseases, blood diseases, neoplastic diseases and edema.

2. What you need to know before you use TRİAVER?

DO NOT USE TRİAVER if;

- you are allergic to triamcinolone acetonide or TRİAVER components,
- you are having an infection,

- you have an unknown cause (idiopathic) thrombocytopenic purpura (if you have bleeding)

TRİAVER should not be administered intravenously (intravenously), intrathecal epidural (from the back to the spinal cord area) or intraocularly.

USE TRİAVER CAREFULLY if;

- you have recently had an infection
- you have a blood clotting problem,
- you have a disease (osteoporosis) that causes fragility in the bones,
- you have a disease such as thyroid dysfunction or cirrhosis,
- you have a mental disorder,
- you have had kidney failure, peptic ulcer, diabetes, tuberculosis, bowel disease, cancer, epilepsy, myasthenia gravis (a disease manifested by a feeling of excessive fatigue in the muscles) or glaucoma (elevation of intraocular pressure),
- you have high blood pressure or have heart failure,
- you have chickenpox or measles,
- you are pregnant or breastfeeding your baby,

If these warnings are applicable to you even for any period of time in the past, please consult your doctor.

Avoid straining your joints even if TRİAVER alleviates your symptoms. The inflammation that caused the symptoms may not have fully healed.

TRİAVER may cause increased blood pressure, water and salt retention, increased potassium and calcium excretion, so salt restriction and potassium supplements may be required in your diet.

If you are receiving high-dose corticosteroid therapy, do not get vaccinated.

Use of TRİAVER with food and drinks

TRİAVER has no interaction with food and drink: however, dietary salt restrictions and potassium supplements may be required.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

If you are pregnant; you can use TRİAVER only if your doctor decides that it is a strict requirement.

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

Breast-feeding

Consult your doctor or your pharmacist before using the drug.

If you are breastfeeding: you can use TRİAVER only if your doctor decides for strict necessity.

Driving and using machines

It is not known whether TRİAVER affects the ability to drive or use machines; however, be careful when driving and using machines as TRİAVER can cause eye problems and dizziness.

Important information about some excipients present in TRİAVER

It should not be administered to preterm babies and newborns due to its benzyl alcohol content. It can cause toxic reactions and allergic reactions in infants and children up to 3 years old.

Each 1 ml suspension contains less than 23 mg sodium (6.6 mg sodium chloride); so it's basically "sodium free."

Use with other medicines

If you are taking any of the following medicines while using TRİAVER, you must inform your doctor:

- Aspirin, ibuprofen or other non-steroidal anti-inflammatory (NSAID) drugs (corticosteroids may increase the risk of gastrointestinal bleeding associated with these drugs),
- Muscle relaxants
- Antibiotics called macrolide group (eg claritoramycin, erythromycin, azithromycin),
- Antifungal drugs (ketoconazole, amphetoricin),
- Blood thinners such as warfarin,
- Oral contraceptives or drugs used in hormone replacement therapy,
- Human growth hormone (eg somatrem),
- Cyclosporine, which suppresses the immune system,
- Medicines used for high blood pressure (blood pressure) or irregular heartbeat (eg digoxin),
- Medicines used to treat myasthenia gravis (a disease that manifests itself with a feeling of excessive fatigue in muscles)
- Medicines used for epilepsy or other seizures (eg phenytoin),
- Medicines used to treat tuberculosis (tuberculosis) (eg isoniazid, rifampicin),
- Medicines used in diabetes,

- Cholestyramine used in the treatment of high cholesterol,
- Drugs used in thyroid problems.

Before you undergo any surgical intervention or anesthetic intervention, tell your doctor or dentist that you are receiving TRİAVER treatment.

Corticosteroid group drugs, including TRİAVER, reduce the response to skin tests.

If you have been vaccinated recently or will be vaccinated during TRİAVER treatment, you should inform your doctor.

If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.

3. How to use TRİAVER?

Instructions for appropriate use and dose / administration frequency:

DOSE REQUIREMENTS ARE CHANGED, THE DOSE SHOULD BE ADJUSTED ACCORDING TO THE DISEASE AND THE PATIENT'S RESPONSE.

Always use TRİAVER as your doctor has told you. If you are not sure, you should consult your doctor or pharmacist.

Systemic use (Treatment areas other than joint diseases)
The recommended dose ranges from 40-80 mg. Your doctor will determine your dose based on your illness and treatment response.
In patients with hay fever or pollen asthma, a single injection at a dose of 40-100 mg can be relieved for an entire pollen season.

Local use (in joint diseases)
The dose to be applied into the joint or tendon sheaths varies depending on the size of the joint and the discomfort treated. Your doctor will determine the dosage that is right for you. 2.5-10 mg in small joints. In large joints, doses up to 40 mg can be given.

Route and method of administration:

It should be administered to large muscles by deep injection or into the joint.
It should never be administered intravenously, intradermally, intraocularly, intraocularly, epidurally or intrathecally.

Various age groups
Use in children:

TRIAVER should not be administered to children under 6 years of age.

Use in elderly:

When TRİAVER is administered to patients over 65 years of age, patients should be closely monitored in terms of exacerbation of side effects.

Special conditions
Renal/Hepatic impairment:

In patients with renal or hepatic impairment, TRİAVER should be administered with caution.

If you have the impression that the efficacy of TRİAVER is too strong or too weak, talk to your doctor or pharmacist.

If you have used more TRİAVER than you should

If you have used more TRİAVER than you should, talk a doctor or pharmacist.

If you forget to use TRİAVER

Your doctor will decide when to apply the missed dose.

It is important to follow your doctor's instructions for the new administration time of the following dose.

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

Effects which may occur when treatment with TRİAVER is discontinued

The effects that may occur when the treatment is terminated are not known.

4. What are the possible side effects?

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

If you notice any of the following, stop using TRİAVER and inform your doctor IMMEDIATELY, or apply to the emergency service of the nearest hospital:

- Hypersensitivity reactions (allergic reactions) with symptoms such as itching, skin rash, edema in the throat.
- Hypersensitivity reactions
- Blood clot formation due to inflammation of the veins

These are all very serious side effects.

If you have one of these, you have a serious allergy to TRİAVER. You may need an emergency medical intervention or hospitalization.

All of these very serious side effects are very rare.

If you notice any of the following, tell your doctor immediately or contact the emergency department of the nearest hospital:

- Irregularity in your heartbeat, heart failure, cardiovascular problems

- Increase in your blood pressure
- Salt and fluid retention
- Fragility in bones, late healing in fractures
- Ulcer, pancreatic inflammation
- Indigestion
- Fungal infection in the digestive system
- Menstrual irregularities
- Suppression of growth in children
- Increased need for drugs in diabetes
- Eye problems
- Aggravation or masking of the infection
- Irregularity in the heartbeat and ECG (recording of the electrical activity of the heart), potassium loss, which can lead to changes
- Hypokalemic alkalosis
- Mass loss in muscles
- Epilepsy (epilepsy)
- Convulsion
- Increased intracranial pressure with papilla edema usually seen after treatment

All these are serious side effects. Emergency medical attention may be required. Serious side effects are very rare.

Tell your doctor if you notice any of the following:

- Weakness in the muscles, weakness
- Delay in wound healing
- Skin thinning, easy bruising
- Dizziness, headache, insomnia, mental breakdown (depression), mood changes, personality changes
- Problems in the application area
- Fainting
- Abdominal bloating
- Ulcerative esophagus inflammation
- Exacerbation of pre-existing psychiatric condition
- Excessive emotions such as joy, trust, strength
- Psychotic symptoms
- Cushingoid condition development

- Decreased carbohydrate tolerance
- The emergence of latent diabetes (diabetes)
- Negative nitrogen balance due to increased blood sugar levels, sugar in urine and protein catabolism

These are mild side effects of TRİAVER.

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

5. How to store TRİAVER

Keep TRİAVER out of the sight and reach of children, and in its packaging.

Store between 15-30°C, protected from light.

Use in compliance with the expiry date.

Do not use TRİAVER after the expiration date stated on the packaging.

Expiry Date is the last day of the specified month.

If you notice any defects in the product and / or packaging, do not use TRİAVER.

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This patient information leaflet is approved on .../.../...

THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHICH IT WILL BE ADMINISTERED.

Administration

MUST BE ADMINISTERED UNDER ASEPTIC CONDITIONS.
Before the ampoule is used, its particles must be shaken to obtain a suspension evenly distributed. Before pulling into the injector, it should be checked whether the suspension has agglomeration or granular appearance (agglomeration). The drug, which has remained in freezing degrees before, may have agglomeration and should not be used. To prevent precipitation in the syringe after being drawn into the syringe, the injection should be done without delay. The injection should be done carefully to avoid the possibility of getting into a blood vessel and infecting the infection.

Systemic
In systemic treatment, injection should be done as **deep** as to the **gluteal muscle**, making sure that it is performed intramuscularly. If the intramuscular injection did not done **deeply**, local atrophy can be seen. Injection should be made to the gluteal area unless there is a necessity. Injection into this area should be avoided since local atrophy is seen more by injection into the deltoid region. The shortest needle length should be 3.8 cm for adults. In obese patients, a longer needle may be required. Different locations should be selected for successive injections.

Local
General intraarticular injection technique for the treatment of joints should be done as specified in the basic books on the subject. If excessive fluid is present in the joint, some, but not all, of the synovial fluid should be aspirated to help relieve pain and prevent excessive dilution of the corticosteroid.

When using intraarticular, intrabursal, and injection into the tendon sheaths, local anesthetic is frequently used. Care should be taken not to inject the suspension into surrounding tissues, since such injections (especially in the deltoid region) and injections into the tendon sheaths can cause tissue atrophy.

In the treatment of acute nonspecific tenosynovitis, care must be taken to ensure that the injection is made into the tendon sheath, not the tendon. Epicondylitis (tennis elbow) can be treated by infiltrating the drug into the area of the highest sensitivity.

Unused products or waste materials should be disposed of in accordance with the 'Medical Waste Control Regulation' and 'Packaging and Waste Control Regulation'.