PATIENT INFORMATION LEAFLET

İMEGERIA 10 mmol/20 ml Solution for Injection

Sterile
It is administered intravenously.

- ***Active ingredient:*** 385.9 mg Gadoterate Meglumine equivalent to 279.32 mg Gadoteric acid in 1 mL injection solution There are. 7.718 g Gadoterate Meglumine equivalent to 5.5864 g Gadoteric acid in 20 mL solution for injection There are.
- ***Excipients:*** For injection This

Read all of this leaflet carefully before you are given 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, please ask your doctor or the person giving you İmegeria (theradiologist) or the hospital/MRI-centre personnel.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *During the use of this medicine, when you go to the doctor or hospital, tell your doctor that you are taking this medicine.*
- *Follow these instructions exactly as written. Do not take higher or lower doses of this medicine than prescribed for you.*

In this instruction manual:

Titles are included.

1. What is IMEGERIA and what it is used for

İMEGERIA is in the group of contrast products used for Magnetic Resonance Imaging (MRI). It is used only by intravenous administration.

IMEGERIA is used to improve image quality during magnetic resonance imaging in brain, spine and all other body pathologies.

IMEGERIA improves the image quality and enables the relevant organs to be displayed more clearly and clearly. This medication should be used only in cases where diagnostic information alone is needed and cannot be obtained by non-contrast magnetic resonance imaging.

A single dose contains 1 vial of 20 mL.

2. What you need to know before you are given imegeria

Read the information in this section carefully.
Before using IMEGERIA, you should review the information here with your doctor .

DO NOT USE IMEGERIA in the following situations:

- If any allergy or any of the excipients contained in IMEGERIA if there is,
- If you are allergic to medications containing gadolinium, such as other contrast medications used for MRI imaging if there is,

Before entering the MRI device, remove all metal accessories. If you use a pacemaker or vascular clip, tell your doctor. Since MRI machines have very strong magnets, this information is important to prevent serious problems.

USE IMEGERIA WITH CARE in the following situations:

- If you have had a reaction to contrast medication during a previous exposure. if you showed
- If you have allergies (asthma, excessive itching, hay fever) like),
- If you are taking Beta-blockers (a medicine used for heart and high blood pressure, such as metoprolol)
- If you have severe kidney failure if there is,
- If you have recently had liver transplant surgery or are planning a liver transplant,
- If you have a fainting problem or Inform your doctor if you are being treated for epilepsy.
- severe kidney failure and are planning a liver transplant operation, see your doctor. inform.

In all these cases, your doctor or radiologist will use IMEGERIA, taking into account the benefits of the drug and the risks it will pose. If your doctor or radiologist uses IMEGERIA, he/she will take the necessary precautions and follow you closely during the application.

Your doctor or radiologist may order a blood test to make sure your kidneys are working properly when deciding to use Imegeria, especially if you are over 65 years old.

Newborns and children
In newborns up to 4 weeks old and babies up to 1 year old, IMEGERIA will be used after a careful evaluation by the doctor, as kidney functions are not fully developed.

Before the examination, remove any metal objects you may have on you. If:
- Heart battery
- Vascular clip
- Infusion pump
- Nerve stimulator
- Cochlear implant (implant in the inner ear)

- Tell your doctor or radiologist, especially if there is any suspicious metallic foreign material inside the eye.

This is important because magnetic resonance imaging devices use very strong magnetic fields, which can cause very serious problems.

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

Using IMEGERIA with food and drink

IMEGERIA has no known interactions with food and beverages. However, consult your attending physician or radiologist about not eating or drinking anything before the shooting.

Pregnancy

Consult your doctor or pharmacist before using this medication.
If you are pregnant, may be pregnant, or your period is late, tell your doctor or radiologist immediately.

IMEGERIA should not be used during pregnancy unless absolutely necessary.
If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

IMEGERIA may pass into your milk. Your doctor will decide whether you will continue to breastfeed your baby for 24 hours after using IMEGERIA.

Driving and using machines

There is no data on the effects of IMEGERIA on your ability to drive. If you feel unwell (nauseous) after the shot, you should not drive or use machinery.

Use with other drugs

If you are currently taking or have recently used any prescription or non-prescription medicine, especially a medicine to treat heart and high blood pressure (such as beta-blockers, vasoactive substances, angiotensin converting enzyme inhibitors, angiotensin II receptor antagonists), please consult your doctor or radiologist. Please provide information about these.

Please inform your doctor or pharmacist if you are currently using or have recently used any prescription or non-prescription medicine, especially a medicine to treat heart and high blood pressure (such as beta-blockers).

3. How is IMEGERIA used?

Instructions for proper use and dosage/frequency of application:

Your doctor or radiologist will determine the dose of your medicine depending on your disease and administer it to you.

Application route and method:

IMEGERIA is administered as an intravenous injection.

You will be under the supervision of a doctor during the application . . Your intravenous line will be left open to administer the necessary medication in case of any emergency. If you have any allergies during the application, the administration of IMEGERIA will be stopped.

IMEGERIA can be administered manually or via an automatic injector. In newborns and infants, the medicine will be given by hand only.

The application will be performed in the hospital or imaging center. Those who do the shooting know the precautions that need to be taken regarding the application and are aware of the possible inconveniences that may arise.

Different age groups:

IMEGERIA can be used in children.
In newborns up to 4 weeks old and babies up to 1 year old, IMEGERIA will be used after a careful evaluation by the doctor, as kidney functions are not fully developed.
If IMEGERIA is to be used in these age groups, only a single dose should be administered and a second dose should not be administered for 7 days.
It is not recommended to use IMEGERIA in angiography in patients under 18 years of age.

Use in the elderly:
If you are 65 years of age or older, no dose adjustment is required. However, you may be asked to have blood tests to make sure your kidneys are working properly.

Special use cases:

Kidney and liver failure:
The use of IMEGERIA is not recommended in patients with severe renal failure and in patients with or planned liver transplantation. However, if IMEGERIA is to be used, only a single dose should be administered and a second dose should not be administered for 7 days.

If you use more IMEgeria than you should

It is unlikely that you will be given more doses than you should use. IMEGERIA is applied by people trained in this field. When IMEGERIA is used more than necessary, it is eliminated from the body by hemodialysis (blood purification).

If you forget to use IMEGERIA

IMEGERIA is a product used for diagnostic purposes and is administered to you in the clinic by a healthcare professional. Therefore, there is no possibility of forgetting to use IMEGERIA.

4. Possible side effects What are they?

Like all medicines, side effects may occur in people who are sensitive to the ingredients contained in IMEGERIA.

You will be kept under observation for at least half an hour after the application. Most side effects occur immediately or sometimes with a delay. Some effects may occur up to seven days after IMEGERIA injection.

Your risk of having an allergic reaction to IMEGERIA is low. These reactions can be serious and cause shock (an allergic reaction that can endanger your life).

The following symptoms may be the first signs of shock. If you feel any of these, notify your doctor, radiologist or healthcare professional immediately:

- swelling of the face, mouth, or throat, which may make it difficult for you to swallow or breathe
- swelling of the hands or feet
- dizziness [hypotension (low blood pressure)]
- difficulty breathing
- wheezing
- cough
- itching
- runny nose
- sneeze
- stinging sensation in the eye
- hives
- skin rash

Side effects are listed as shown in the following categories:

Very common : It can be seen in at least 1 in 10 patients.

Common : It may occur in less than 1 in 10 patients, but in more than 1 in 100 patients.

Uncommon : It may occur in less than 1 in 100 patients, but in more than 1 in 1,000 patients.

Rare : It may occur in less than 1 in 1,000 patients, but in more than 1 in 10,000 patients.

Very rare : It may occur in less than 1 in 10,000 patients.

Unknown (cannot be estimated from available data)

Unusual

- hypersensitivity
- anxiety (anxiety disorder)
- headache
- unusual taste in mouth
- dizziness
- sleeping state
- tingling, hot, cold and/or painful sensations

- low or high blood pressure
- nausea (feeling of vomiting)
- stomach ache
- debris
- heat, cold
- fatigue
- Discomfort, reaction, chills, swelling at the injection site (injection site), product spreading outside the blood vessels and causing inflammation (redness and local pain)

Rare
- fainting (a feeling of dizziness and loss of consciousness)
- eyelid swelling
- palpitation
- sneeze,
- vomiting (being sick)
- diarrhea
- increased salivation
- hives, itching, sweating
- chest pain, chills

Very rare
- Anaphylactic (severe allergic reaction) or anaphylactic-like reactions
- agitation (state of restlessness)
- coma, convulsions, seizure (brief loss of consciousness), olfactory dysfunction (usually perception of foul odor), tremors
- conjunctivitis (a type of eye inflammation, eye inflammation), eye redness, blurred vision, increased tear secretion
- cardiac arrest, fast or abnormally slow heartbeat, irregular heartbeat, dilation of blood vessels, pallor
- respiratory arrest, pulmonary edema (accumulation of fluid in the lungs), difficulty breathing, nasal congestion, dry throat, feeling of tightness in the throat accompanied by a feeling of suffocation, cough, breathing spasms, swelling of the throat
- eczema, skin rash, swelling of the lips and mouth
- muscle cramps, muscle weakness, back pain
- weakness, chest discomfort, fever, facial edema, fatigue, coldness, discomfort at the injection site, spread of the product outside the blood vessels, which may cause tissue death at the injection site, inflammation of the vessel
- decreased blood oxygen level

Unknown
- Nephrogenic systemic fibrosis (a disease that causes hardening of the skin and can also affect soft tissues and internal organs)

There have been reports of nephrogenic systemic fibrosis (a disease that causes hardening of the skin and can also affect soft tissues and internal organs), mostly in patients receiving concomitant IMEGERIA and other gadolinium-containing contrast media. If you notice a change in the color and/or thickness of your skin on any part of your body in the weeks after

the MRI examination, notify the radiologist performing the examination.

The following side effects have been reported with other intravenously administered contrast agents used for MRI. The frequency of these side effects is unknown.

- blood cell destruction
- confusion
- temporary blindness, eye pain
- tinnitus, earache
- asthma
- dry mouth
- bullous dermatitis (a type of skin disease in which fluid sacs form)
- urinary incontinence
- acute kidney failure
- death of cells responsible for filtering urine in the kidney
- changes in the electrocardiogram (PR interval prolongation)
- changes in blood values (increase in blood iron, bilirubin and serum ferritin)
- abnormal liver function test conclusion

Reporting side effects
If you experience any side effects, whether listed in the Instructions for Use or not, talk to your doctor, pharmacist or nurse. Also, report the side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Reporting" icon on the website www.titck.gov.tr or by calling the side effect reporting line at 0 800 314 00 08. By reporting any side effects that occur, you will contribute to obtaining more information about the safety of the medicine you are using.

If you experience any side effects not mentioned in this instruction manual, inform your doctor or pharmacist.

5. İMEGERIA storage

Keep IMEGERIA out of sight and reach of children and in its packaging.

IMEGERIA should be stored at 25°C, away from light.

If solidification occurs in the vial due to exposure to cold, bring Imegeria to room temperature before use. If left to stand at room temperature for at least 90 minutes, IMEGERIA should turn into a clear, colorless to yellow solution. Before use, inspect the product to ensure that all solids have dissolved and that the container and lid are not damaged. If solids persist, discard the vial.

Use in accordance with expiration dates.

Do not use IMEGERIA after the expiry date stated on the bottle and box.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Destroying the remaining IMEGERIA is not something that will be requested from you. Ask your pharmacist what you should do if this happens. What will be done here will be aimed at protecting the environment.

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Before IMEGERIA administration, it is recommended that all patients be screened for renal dysfunction with laboratory tests.

There have been reports of nephrogenic systemic fibrosis (NSF) associated with the use of some gadolinium-containing contrast agents in patients with acute or chronic severe renal dysfunction (GFR <30 mL/min/1.73 m²). Patients undergoing liver transplantation are at particular risk because the incidence of acute renal failure is high in this population.

Because of the possibility that NSF may occur with IMEGERIA in patients with severe renal impairment and in patients undergoing perioperative liver transplantation, its use should be avoided unless diagnostic information is necessary and can be obtained by non-contrast MRI. If the use of IMEGERIA cannot be avoided, the dose should not exceed 0.1 mmol/kg body weight.
Due to the lack of knowledge regarding repeated administration, IMEGERIA injections should not be repeated unless the interval between injections is at least 7 days.

Hemodialysis application shortly after the application of IMEGERIA may be useful to remove IMEGERIA from the body. There are no findings to support initiating hemodialysis for the prevention or treatment of NSF in patients not receiving hemodialysis treatment.

In newborns up to 4 weeks of age and infants up to 1 year of age, IMEGERIA should be used after careful evaluation and in doses not exceeding 0.1 mmol/kg, as renal functions are not fully developed. More than one dose should not be used in the same shot.
Since there is not enough information about repeated doses, the second dose should not be administered for 7 days after the first application.

Since gadoteric acid excretion may be insufficient in the elderly, it is important to evaluate renal

functions in patients aged 65 and over.

IMEGERIA should not be used during pregnancy except in clinical situations where it is needed.

In breastfeeding mothers, the doctor and the mother should decide together whether to continue breastfeeding for 24 hours after IMEGERIA application.

Adhesive labels on the vial must be attached to the patient's record to ensure accurate recording of the gadolinium-containing contrast medium used. The dose used should also be recorded in the patient record. If electronic patient records are maintained, the batch number and dose should be entered in the patient record.