PATIENT INFORMATION LEAFLET

GADODİEM 287 mg/ml vial containing solution for IV injection
Sterile, Apyrogen

It is used via intravenal administration.

- ***Active substance:*** Each 1 mL contains 287 mg gadodiamide (equivalents to 0.5 mmol/mL).
  10 mL contains 2.87 g (5.0 mmol) gadodiamide
  15 mL contains 4.31 g (7.5 mmol) gadodiamide
  20 mL contains 5.74 g (10.0 mmol) gadodiamide

- ***Excipient(s):*** Product contains caldiamide sodium, sodium hydroxide (pH adjuster), hydrochloric acid (pH adjuster) and water for injection.

Read all of this PATIENT INFORMATION LEAFLET carefully before you are given GADODİEM 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 your pharmacist.*
- *This medicine has been prescribed for you personally, you should not pass it on to others.*
- *During usage of this medicine, when you go to hospital or doctor please tell your doctor that you have used this medicine.*
- *Follow these instructions exactly. Do not use **high dosage or low dosage** of product except for recommended dosage for you.*

In this patient information leaflet;

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

This medicine is for diagnostic use only.

GADODİEM is a contrast medium which is used in Magnetic Resonance Imaging (MRI) examinations of the brain or spine, and for whole body examinations like the head and neck region, the thoracic cavity including the heart, extremities (arms and legs), organs in the abdominal cavity (prostate, urinary bladder, pancreas and liver), kidney, female breast, musculoskeletal system and blood vessels.

GADODİEM is presented in cartoon box which contains colorless Type I glass vial closed with grey rubber stoppers and sealed with blue colored Alu-PP "flip-off" caps. This product is supplied as 10 mL, 15 mL and 20 mL package size.

GADODİEM can help some medical conditions to be seen more clearly. This helps the doctor to find and examine these conditions more easily, and can improve the information needed to make a diagnosis.

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

THERE IS NO INTRATHECAL USAGE.
Intrathecal usage causes to occur convulsion, coma and sensory and motor neuron damages.

DO NOT USE GADODİEM in these conditions below;

- If you are allergic (hypersensitive) to gadodiamide or any of the other ingredients of GADODİEM
- If you suffer from severe kidney problems, or if you are a patient who is about to have or has recently had a liver transplant

  Usage of GADODİEM in patients with these conditions has been associated with a disease called nephrogenic systemic fibrosis (NSF). NSF is a disease involving thickening of the skin and connective tissues. NSF may result in severe joint immobility, muscle weakness or may affect the normal working of internal organs which may potentially be life-threatening.

- GADODİEM should also not be given to newborn babies up to age of 4 weeks.

PLEASE USE GADODİEM CAREFULLY in these conditions below:

- If you have a heart pacemaker or any implants containing iron in your body
- If you have previously experienced a severe reaction after receiving contrast media
- If you have or have had any allergies (e.g. allergies to seafood, hay fever, nettle rash), asthma or other allergic respiratory disorders.
- If you suffer from heart diseases or disorders of the central nervous system (epilepsy or brain lesions).
- If you suffer from moderate kidney problems.

If you have any of these conditions mentioned above, please tell this situation to your doctor.
Tell your doctor if:
- Your kidneys do not work properly
- You have recently had or soon expect to have a liver transplant

Before you receive GADODİEM, you will need to have a blood test to check whether your kidneys are working well.
GADODİEM should not be used in newborn babies up to the age of 4 weeks. As kidney function is immature in infants up to 1 year of age, GADODİEM will only be used in infants after careful consideration by the doctor.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Usage of GADODİEM with foods and drinks
Please follow your doctor's recommendations.

Pregnancy
Consult your doctor or your pharmacist before taking this medicine.

GADODİEM should not be used during pregnancy unless strictly necessary.

Please consult your doctor if you think you are or might become pregnant during your treatment.

Breast-feeding
Consult your doctor or your pharmacist before taking this medicine.
Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding should be discontinued for at least 24 hours after you receive GADODİEM.

Driving and using machines
Driving should be avoided since nausea may occur after the investigation.

Important information about some of excipients in this medicine
Glass bottle of this product contains latex rubber. This material can cause severe allergic reactions.

This medicinal product contains 0.62 mg/mL Sodium. This needs to be considered for people on a controlled sodium diet.

Taking with other medicines
Tell your doctor if you are having blood samples taken on the same day and within 12-24 hours after GADODİEM injection. GADODİEM interferes with some of the methods commonly used for measuring content of electrolytes (e.g. iron and calcium) in blood.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. How to use GADODİEM?

Suitable usage and instructions for dosage/ administration frequency:

The amount injected will depend upon your weight and what part of the body you are having examined. The usual dose is 0.2 mL/kg body weight or occasionally up to 0.6 mL/kg body weight. Even if you weigh more than 100 kg you will normally not receive more than 20 mL or for some conditions up to 60 mL.

Dosage in special patient groups
You should not be given GADODİEM if you suffer from severe kidney problems or if you are a patient who is about to have or has recently had a liver transplant. GADODİEM should also not be used in newborn babies up to the age of 4 weeks.

If you have moderate kidney problems, you should only receive one dose of GADODİEM during a scan. In this case, if it is necessary, a second injection can be given to you at least 7 days later.

As kidney function is immature in infants up to 1 year of age, infants should only receive one dose of GADODİEM during a scan and should not receive a second injection for at least 7 days.

Your doctor will determine your medicines dosage depends on your condition and will administer to you.

It is not necessary to adjust your dose if you are 65 years of age or older but you will have a blood test to check whether your kidneys are working well.

Administration route and method:
GADODİEM will be injected into one of your veins usually as a single injection before or during your MRI examination. Occasionally a second injection may be needed to obtain additional diagnostic value.

If you have any further questions on the use of this product, consult your doctor or your pharmacist.

If you take more of GADODİEM than you should
This product will be administered under control of doctor and in clinic.

If you forget to take GADODİEM
Please follow your doctor's instructions about when GADODİEM will be administered. This product will be administered to you in control of doctor and in clinic.

Effects seen when GADODİEM treatment is ended:
If you have notice any problem after administration of GADODİEM, please consult to your doctor.

4. What are possible side effects?

Like all medicines, GADODİEM can cause side effects, although not everybody gets them.

Common (side effects which are seen in more than 1 in 100 people, less than 1 in 10 people):
- Coolness or local pressure in connection with injection
- Transient sensation of pain at the injection site
- Headache
- Nausea.

Uncommon (side effects which are seen in more than 1 in 1000 people, less than 1 in 100 people):
- Allergy-like skin and mucous membrane reactions, hypersensitivity
- Dizziness.
- Tingling sensations.
- A transient change in your sense of taste.
- Vomiting.
- Diarrhea.

- Flushing.
- Itching.

Rare (side effects which are seen in more than 1 in 10000 people, less than 1 in 1000 people):
- A transient change in your sense of smell.
- Cramps.
- Drowsiness.
- Difficulty in breathing.
- Pain in the joints.
- Trembling.
- Anxiety.
- Visual disturbances.
- Chest pain.
- Acute renal failure.
- Coughing.
- Rash and hives.
- Swellings, including face swelling.
- Fever.
- Shivering.

Not known (frequency cannot be estimated from the available data)
- ? There are notifications about nephrogenic systemic fibrosis (This cause skin thickening and may affect soft tissues and internal organs.)
- Anaphylactic/anaphylactoid reactions
- Rapid pulse.
- Sneezing.
- Irritation in the throat.
- Severe difficulty in breathing.

Please consult your doctor immediately if the conditions below about angioedema are occurred:
- Face, tongue and throat (pharynx) swellings
- Dysphagia
- Rash and difficulty in breathing

Most of the allergic reactions occur within half an hour after injection. In rare cases side effects may ocur after hours or days.

If any of these side effects get serious or if you face any other side effects which are not mentioned in this leaflet please inform your doctor or your pharmacist.

If you get any side effects, talk to your doctor, your pharmacist or your nurse. Besides you can directly inform TÜFAM of side effects by click on “Drug Side Effect Notification” icon included www.titck.gov.tr site and you can call side effect notification line numbered with 0 800 314 00 08.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. Storage of GADODİEM

Keep out of the sight and reach of children.

Please use this medicine in line with the expiry date.

Do not use GADODİEM *after the expiry date which is stated on the label.*
Store in room temperature below 25°C and protect from light. Store the vial in the outer carton in order to protect from light.

Do not freeze.

Do not use GADODİEM if you notice severe discoloration, the occurrence of particulate matter or a defective container.

From a microbiological point of view, the product should be used immediately after opening. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

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THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY:

Each vial of contrast medium is intended for single use. Any unused portions must be discarded.

If this medicinal product is intended to be used with an automatic application system, its suitability for the intended use has to be demonstrated by the manufacturer of the medical device. Instructions for use of the medical device must be followed absolutely.

Prior to administration of GADODİEM, all patients should be screened for renal dysfunction by obtaining laboratory tests.
There have been reports of nephrogenic systemic fibrosis (NSF) associated with use of GADODİEM and some other gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR < 30 mL/min/1.73 m^2). Patients undergoing liver transplantation are at particular risk since the incidence of acute renal failure is high in this group. Therefore GADODİEM must not be used in patients with severe renal impairment, in patients in the perioperative liver transplantation period.

GADODİEM should also not be given to newborn babies up to the age of 4 weeks.

The risk for development of NSF in patients with moderate renal impairment (GFR 30–59 ml/min/1.73 m^2) is unknown; therefore, GADODİEM should be only used after careful risk-benefit evaluation in these patients. Dose should not exceed 0.1 mmol/kg body weight in patients with moderate renal impairment. More than one dose should not be used during a scan. Because of the lack of information on repeated administration, GADODİEM injections should not be repeated unless the interval between injections is at least 7 days.

Due to immature renal function in infants up to 1 year of age, GADODİEM should only be used in these patients after careful consideration at a dose not exceeding 0.1 mmol/kg body weight. More than one dose should not be used during a scan. Because of the lack of information on repeated administration, GADODİEM injections should not be repeated unless the interval between injections is at least 7 days.

GADODİEM should not be given to newborn babies up to age of 4 weeks.

As the renal clearance of gadodiamide may be impaired in the elderly, it is particularly important to screen patients aged 65 years and older for renal dysfunction.

Hemodialysis shortly after GADODİEM administration may be useful at removing GADODİEM from the body. There is no evidence to support the initiation of hemodialysis for prevention or treatment of NSF in patients not already undergoing hemodialysis.

GADODİEM should not be used during pregnancy unless the clinical condition of the woman requires use of gadodiamide.

Breast-feeding should be discontinued for at least 24 hours after the administration of GADODİEM

The peel-off tracking label on the vials/bottles and syringes should be stuck onto the patient record to enable accurate recording of the gadolinium contrast agent used. The dose used should also be recorded.