**MEDICATION GUIDE**
**DOTAREM® (doh TAH rem)**
**(gadoterate meglumine)**
**Injection for intravenous use**

**What is DOTAREM?**

- DOTAREM is a prescription medicine called a gadolinium-based contrast agent (GBCA). DOTAREM, like other GBCAs, is injected into your vein and used with a magnetic resonance imaging (MRI) scanner.
- An MRI exam with a GBCA, including DOTAREM, helps your doctor to see problems better than an MRI exam without a GBCA.
- Your doctor has reviewed your medical records and has determined that you would benefit from using a GBCA with your MRI exam.

**What is the most important information I should know about DOTAREM?**

- GBCAs like DOTAREM may cause serious side effects including death, coma, encephalopathy, and seizures when it is given intrathecally (injection given into the spinal canal). It is not known if DOTAREM is safe and effective with intrathecal use. DOTAREM is not approved for this use.
- DOTAREM contains a metal called gadolinium. Small amounts of gadolinium can stay in your body including the brain, bones, skin and other parts of your body for a long time (several months to years).
- It is not known how gadolinium may affect you, but so far, studies have not found harmful effects in patients with normal kidneys.
- Rarely patients have reported pains, tiredness, and skin, muscle or bone ailments for a long time, but these symptoms have not been directly linked to gadolinium.
- There are different GBCAs that can be used for your MRI exam. The amount of gadolinium that stays in the body is different for different gadolinium medicines. Gadolinium stays in the body more after Omniscan or Optimark than after Eovist, Magnevist or MultiHance. Gadolinium stays in the body the least after Dotarem, Gadavist or ProHance.
- People who get many doses of gadolinium medicines, women who are pregnant and young children may be at increased risk from gadolinium staying in the body.
- Some people with kidney problems who get gadolinium medicines can develop a condition with severe thickening of the skin, muscles and other organs in the body (nephrogenic systemic fibrosis). Your healthcare provider should screen you to see how well your kidneys are working before you receive DOTAREM.

**Do not receive DOTAREM if you have had a severe allergic reaction to DOTAREM.**

**Before receiving DOTAREM, tell your healthcare provider about all your medical conditions, including if you:**

- have had any MRI procedures in the past where you received a GBCA. Your healthcare provider may ask you for more information including the dates of these MRI procedures.
- are pregnant or plan to become pregnant. It is not known if DOTAREM can harm your unborn baby. Talk to your healthcare provider about the possible risks to an unborn baby if a GBCA such as DOTAREM is received during pregnancy.
- have kidney problems, diabetes, or high blood pressure.
- have had an allergic reaction to dyes (contrast agents) including GBCAs.

**What are possible side effects of DOTAREM?**

- **See "What is the most important information I should know about DOTAREM?"**
- **Allergic reactions. DOTAREM can cause allergic reactions that can sometimes be serious. Your healthcare provider will monitor you closely for symptoms of an allergic reaction.**

**The most common side effects of DOTAREM include: nausea, headache, pain, or cold feeling at the injection site, and rash.**

These are not all the possible side effects of DOTAREM.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective uses of DOTAREM.**
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider for information about DOTAREM that is written for health professionals.

**What are the ingredients in DOTAREM?**
**Active ingredient: gadoterate meglumine**
**Inactive ingredients: DOTA, water for injection**
Manufactured by: Catalent (glass pre-filled syringes), Liebel-Flarsheim Company LLC (plastic pre-filled syringes and vials) and Recipharm (vials) for Guerbet
For more information, go to www.guerbet-us.com or call 1-877-729-6679.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Rev. 1/2024