

MEDICATION GUIDE

Gadobutrol (GAD oh BUE trol) Injection Injection for intravenous use

What is the most important information I should know about gadobutrol injection?

- GBCAs like Gadobutrol injection 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 Gadobutrol injection is safe and effective with intrathecal use. Gadobutrol injection is not approved for this use.
- Gadobutrol injection 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, Gadobutrol injection, 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 gadobutrol injection.

What is gadobutrol injection?

- Gadobutrol injection is a prescription medicine called a gadolinium-based contrast agent (GBCA). Gadobutrol injection, like other GBCAs, is injected into your vein and used with a magnetic resonance imaging (MRI) scanner.
- An MRI exam with a GBCA, including gadobutrol injection, 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.

Do not receive gadobutrol injection if you have had a severe allergic reaction to gadobutrol injection.

Before receiving gadobutrol injection, 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 gadobutrol injection can harm your unborn baby. Talk to your healthcare provider about the possible risks to an unborn baby if a GBCA such as gadobutrol injection 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 the possible side effects of gadobutrol injection?

- See “What is the most important information I should know about gadobutrol injection?”
- **Allergic reactions.** Gadobutrol injection can cause allergic reactions that can sometimes be serious. Your healthcare provider will monitor you closely for symptoms of an allergic reaction.
- **A serious lung problem called acute respiratory distress syndrome (ARDS).** Call your healthcare provider right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing after receiving gadobutrol injection.

The most common side effects of gadobutrol injection include: headache, nausea, dizziness.

These are not all the possible side effects of gadobutrol injection.

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 use of gadobutrol injection.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider for information about gadobutrol injection that is written for health professionals.

What are the ingredients in gadobutrol injection?

Active ingredient: gadobutrol

Inactive ingredients: calcobutrol sodium, tromethamine, hydrochloric acid (for pH adjustment) and water for injection

Manufactured for:



Lake Zurich, IL 60047

www.fresenius-kabi.com/us

For more information, call Fresenius Kabi USA, LLC at 1-800-551-7176.

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