INJECTION OF GADOLINIUM-BASED CONTRAST AGENT INFORMED CONSENT

Huntington-Hill Imaging Centers

☐ **Huntington-Hill Imaging Center** Cordova

☐ **Huntington-Hill Imaging Center** Fair Oaks

☐ **Huntington-Hill Imaging Center** Glendora

☐ **Huntington-Hill Imaging Center** West Covina

Patient Name: _____

Procedure Ordered: _____

Your doctor has referred you to our imaging center for a Magnetic Resonance Imaging (MRI) examination requiring an injection of Gadolinium-Based MRI contrast. Contrast enhances the visualization of tissues to help diagnose a medical condition.

<u>Risks of gadolinium contrast are rare,</u> but may include the following:

- Allergic reaction, nausea, headache, dizziness, metallic taste in mouth, tingling in arm, feeling hot and back pain (Refer to section 5 of the attached Medication Guide for the most common side-effects associated with the intravenous gadolinium contrast to be administered.)
- Insertion of the needle may cause minor pain, bruising and/or infection at the injection site.
- Nephrogenic Systemic Fibrosis (NSF). Patients with severe kidney failure or on dialysis could be at risk for developing NSF, a rare fibrosing condition of the skin and connective tissues which can inhibit your ability to move, adversely affect other organs, and can be potentially life threatening. If you have been diagnosed with kidney failure or are receiving dialysis treatments please inform the technologist.

<u>Alternatives to Intravenous Contrast:</u> An MRI without contrast or other tests may be possible; however, such procedures may not produce the same diagnostic result achieved by utilizing intravenous Contrast Agents.

By signing and dating this form, I confirm:

- I have read and understood the information provided on this form, including the risks described above, including NSF.
- I have received a copy of the Medication Guide, approved by the U.S. Food and Drug Administration, for the gadolinium contrast agent that will be administered.
- I authorize and consent to an MRI with IV gadolinium contrast.

DATE: _____

PATIENT SIGNATURE: _____

PARENT OR GUARDIAN: _____
(if patient is unable to sign)

WITNESS: _____

*If you'd like information about "What to Expect" before your procedure, videos are available on our website at **www.HillMedical.com**.*

MEDICATION GUIDE
GADAVIST (gad-a-vist)
(gadobutrol) Injection for intravenous use

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

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

Before receiving Gadavist, 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 Gadavist can harm your unborn baby. Talk to your healthcare provider about the possible risks to an unborn baby if a GBCA such as Gadavist 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 Gadavist?
- **See "What is the most important information I should know about Gadavist?"**
- **Allergic reactions. Gadavist 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 Gadavist include: headache, nausea, and dizziness.

These are not all the possible side effects of Gadavist.

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

What are the ingredients in Gadavist?
Active ingredient: gadobutrol

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

Manufactured for Bayer HealthCare Pharmaceuticals Inc.

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For more information, go to www.gadavist.com or call 1-888-842-2937.

This Medication Guide has been approved by the U.S. Food and Drug Administration. 4/2018