

## Dear Valued GAMMAGARD S/D Customer,

We are reaching out with an important update on GAMMAGARD S/D [Immune Globulin Intravenous (Human)] IgA less than 1 microgram per milliliter in a 5% solution. **Takeda has shared in a recent press release that we will stop making GAMMAGARD S/D at the end of December 2027.** GAMMAGARD S/D will be available after this date until supply runs out or product expires. We know that this news may be concerning to some people who rely on GAMMAGARD S/D for their treatment.

### Why is Takeda making this change now?

- GAMMAGARD S/D is made with a process that will not be able to reliably support the future needs of the patient community
- This decision is not related to patient safety

**We're sharing this news now so people using GAMMAGARD S/D can talk with their healthcare team about their options.**

We're also sharing information with doctors who are treating people on GAMMAGARD S/D. As this is recent news, it might take time for your doctor to have information they need to answer your questions.

**Takeda remains committed to supporting the needs of the Primary Immunodeficiency (PI) Community.**

**You may have heard that on June 27, 2025, the FDA approved a new Takeda immune globulin (Ig) therapy called GAMMAGARD LIQUID ERC [Immune Globulin Infusion (Human)]:**

- A liquid formulation that contains a low level of (IgA) with less than or equal to 2 micrograms per milliliter of IgA in a 10% solution
- It is used to treat PI in people two years and older
- It is given in a vein (intravenously) or under the skin (subcutaneously)
- It is made in the same way as our other ready-to-use liquid Ig products, helping to enable a reliable supply from Takeda
- It is expected to become available over time starting in 2026

GAMMAGARD LIQUID ERC is not a replacement for GAMMAGARD S/D. Once it is available, it may be an option for appropriate patients who require a low IgA immunoglobulin therapy.

Your health, safety, and trust are our top priorities. If you have any questions or would like more information, please reach out to your healthcare team or contact us directly at 1-866-861-1750.

Thank you for trusting Takeda as your partner in your care.

Kind regards,

**Rory Bukofzer**

Institutional Franchise Head, U.S. Plasma-Derived Therapies Business Unit, Takeda

### What are GAMMAGARD LIQUID ERC and GAMMAGARD S/D?

- **GAMMAGARD LIQUID ERC** and **GAMMAGARD S/D** are medicines used to treat primary immunodeficiency (PI).
- **GAMMAGARD LIQUID ERC** is for people 2 years and older and given in a vein (intravenously) or under the skin (subcutaneously).
- **GAMMAGARD S/D** is for people 2 years and older and given in a vein.

### IMPORTANT SAFETY INFORMATION

**What is the most important information that I should know about GAMMAGARD LIQUID ERC and GAMMAGARD S/D?**

**GAMMAGARD LIQUID ERC** and **GAMMAGARD S/D** can cause the following serious reactions:

- Severe allergic reactions causing difficulty in breathing or skin rashes
- Severe headache, drowsiness, fever, painful eye movements, or nausea and vomiting
- Decreased kidney function or kidney failure
- Dark colored urine, swelling, fatigue, or difficulty breathing
- Blood clots in the heart, brain, lungs, or elsewhere in the body

**For additional safety information, click for [Information For Patients for GAMMAGARD LIQUID ERC and GAMMAGARD S/D](#), and discuss with your HCP.**

## IMPORTANT SAFETY INFORMATION (cont'd)

### Who should not use GAMMAGARD LIQUID ERC or GAMMAGARD S/D?

- Do not use **GAMMAGARD LIQUID ERC** if you have a known history of a severe allergic reaction to immune globulin or other blood products.
- Do not use **GAMMAGARD S/D** if you have had a severe allergic reaction to **GAMMAGARD S/D**.

### What should I tell my HCP before I start using or while using GAMMAGARD LIQUID ERC, or GAMMAGARD S/D?

- **GAMMAGARD LIQUID ERC** and **GAMMAGARD S/D** can make vaccines (like measles/mumps/rubella or chickenpox vaccines) not work as well for you. Before you get any vaccines, tell your HCP that you take any of these treatments.
- Tell your HCP if you are pregnant, trying to become pregnant, or are breast feeding.

### What are the possible or reasonably likely side effects of GAMMAGARD LIQUID ERC and GAMMAGARD S/D? **GAMMAGARD LIQUID ERC** and **GAMMAGARD S/D** can cause serious side effects. If any of the following problems occur after starting any of these treatments, stop the infusion immediately and contact your HCP or call emergency services:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation of the lining around your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or a blood problem.
- Chest pain or trouble breathing, or blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be a sign of an infection.

The following one or more possible reactions may occur at the site of infusion of **GAMMAGARD LIQUID ERC**. These generally go away within a few hours and are less likely after the first few infusions:

- Mild or moderate pain
- Swelling
- Itching
- Rash
- Redness
- Bruising
- Warmth
- Bleeding

During the infusion of **GAMMAGARD LIQUID ERC**, look out for the first signs of the following common side effects:

- Headache
- Migraine
- Fever
- Fatigue
- Itching
- Rash/hives
- Cough
- Chest pain/tightness
- Pain in extremity
- Diarrhea
- Infusion site leakage
- Joint pain
- Chills/shaking chills
- Dizziness
- Nausea/vomiting
- Faster heart rate
- Upper abdominal pain
- Increased blood pressure
- Muscle cramps
- Sore throat
- Heart murmur
- Asthma
- Ear pain
- Mouth ulcer/sore

The most common side effects of **GAMMAGARD S/D** are:

- Headache
- Nausea
- Chills
- Fatigue
- Fever
- Upper abdominal pain
- Diarrhea
- Back pain
- Infusion site pain
- Sweating
- Flushing

**These are not all the possible side effects. Talk to your HCP about any side effect that bothers you or that does not go away.**

***For additional safety information, including Warnings about Blood Clots, Decreased Kidney Function, and Kidney Failure, click for Information for Patients for [GAMMAGARD LIQUID ERC](#) and [GAMMAGARD S/D](#), and discuss with your HCP.***

**You are encouraged to report negative side effects of prescription drugs to FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

