CGD CASE STUDY:
GINA

Struggles with serious infections
• 38 years old
• X-linked chronic granulomatous disease (CGD) (highly lyonized carrier)
• Last serious infection in 2018

INDICATIONS AND USAGE
ACTIMMUNE® (Interferon gamma-1b) is indicated for reducing the frequency and severity of serious infections associated with chronic granulomatous disease.

Select Safety Information
ACTIMMUNE® is contraindicated in patients who develop or have known hypersensitivity to interferon-gamma, E coli-derived products, or any component of the product.

Please see Important Safety Information on back and the enclosed ACTIMMUNE® Full Prescribing Information.

ACTIMMUNE® is FDA approved specifically for CGD patients. Learn more at ACTIMMUNEhcp.com.
administration of ACTIMMUNE®. Acetaminophen may be used to prevent or partially alleviate the fever and headache, chills, myalgia, or fatigue, which may decrease in severity as treatment continues and may be minimized by bedtime.

Gina’s profile

CASE HISTORY:

Gina is a 38-year-old highly lyonized X-linked CGD patient and mother of a 9-year-old son who was conceived with preimplantation genetic diagnosis before in vitro fertilization to prevent inheritance of the condition. Gina has a family history of recurrent serious infections, resulting in the death of a second-degree male relative. She was diagnosed at age 23, following a 27-day hospital visit for pneumonia. Gina currently takes cephalexin, trimethoprim, and itraconazole to help prevent serious bacterial and fungal infections, as well as hydroxychloroquine to treat lupus-like symptoms.

Despite prophylactic therapy, Gina has been hospitalized for pneumonia and serious infections. In 2014, Gina was hospitalized twice for bacterial pneumonia caused by actinomyces. She was admitted for 7 days for each hospitalization. Her last complication was an abscess, 

From a clinical trial of patients taking ACTIMMUNE® (Interferon gamma-1b) vs placebo, ACTIMMUNE® demonstrated a1,2:

- 67% reduction in relative risk of serious infection (P = .0006)
- 64% reduction in the total number and rate of serious infections, including recurrent infections (P < .0001)
- 67% reduction in hospitalization days (P = .02)

In patients who did not make need to be hospitalized, the average length of stay was 33% shorter for those taking ACTIMMUNE® compared with those taking placebo (32 days vs 48 days, P = .02).

ACTIMMUNE® is the only product approved by the FDA for CGD patients based on a randomized, prospective study.

In 2018, Gina was born.

Select Safety Information

The most common adverse events occurring with ACTIMMUNE® therapy are flu-like symptoms, such as fever, headache, chills, myalgia, or fatigue, which may decrease in severity as treatment continues and may be minimized by bedtime administration of ACTIMMUNE®. Acetaminophen may be used to prevent or partially alleviate the fever and headache.
INDICATIONS AND USAGE
ACTIMMUNE® (Interferon gamma-1b) is indicated:
• For reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease
• For delaying time to disease progression in patients with severe, malignant osteopetrosis

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
• In patients who develop or have known hypersensitivity to interferon-gamma, E coli-derived products, or any component of the product

WARNINGS AND PRECAUTIONS
• ACTIMMUNE should be used with caution in patients with:
  – Pre-existing cardiac conditions, including ischemia, congestive heart failure, or arrhythmia
  – Seizure disorders or compromised central nervous system function; reduce dose or discontinue
  – Myelosuppression, or receiving other potentially myelosuppressive agents; consider dose reduction or discontinuation of therapy
  – Severe renal insufficiency
  – Age <1 year
• Monitoring:
  – Patients begun on ACTIMMUNE before age 1 year should receive monthly assessments of liver function. If severe hepatic enzyme elevations develop, ACTIMMUNE dosage should be modified
  – Monitor renal function regularly when administering ACTIMMUNE in patients with severe renal insufficiency; accumulation of interferon gamma-1b may occur with repeated administration. Renal toxicity has been reported in patients receiving ACTIMMUNE

• Pregnancy, Lactation, and Fertility:
  – ACTIMMUNE should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus
  – Use of ACTIMMUNE by lactating mothers is not recommended. ACTIMMUNE or nursing should be discontinued dependent on the importance of the drug to the mother
  – Long-term effects of ACTIMMUNE on fertility are not known

DRUG INTERACTIONS
• Concomitant use of drugs with neurotoxic, hematotoxic, or cardiotoxic effects may increase the toxicity of interferons
• Avoid simultaneous administration of ACTIMMUNE with other heterologous serum protein or immunological preparations (eg, vaccines)

ADVERSE REACTIONS
• The most common adverse experiences occurring with ACTIMMUNE therapy are “flu-like” symptoms such as fever, headache, chills, myalgia, or fatigue, which may decrease in severity as treatment continues, and may be minimized by bedtime administration of ACTIMMUNE. Acetaminophen may be used to prevent or partially alleviate the fever and headache
• Isolated cases of acute serious hypersensitivity reactions have been observed in patients receiving ACTIMMUNE
• Reversible neutropenia, thrombocytopenia, and elevations of AST and/or ALT have been observed during ACTIMMUNE therapy
• At doses 10 times greater than the weekly recommended dose, ACTIMMUNE may exacerbate pre-existing cardiac conditions, or may cause reversible neurological effects such as decreased mental status, gait disturbance, and dizziness


ACTIMMUNE® is distributed in the US by Horizon Pharma USA, Inc.
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Please see the enclosed ACTIMMUNE® Full Prescribing Information.