ACTIMMUNE® CASE STUDY:

BRANDEN

Finding success with adherence
- 28 years old
- X-linked chronic granulomatous disease (CGD)
- Last hospitalized in 2009

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.

Learn more at ACTIMMUNE.com
Branden’s profile

AGE: 28
CGD INHERITANCE PATTERN: X-linked
AGE AT DIAGNOSIS: 7
THERAPY: trimethoprim-sulfamethoxazole, ACTIMMUNE® (interferon gamma-1b), itraconazole
LAST SERIOUS INFECTION: 2006, staphylococcal infection in the lymph node (neck)
LAST HOSPITALIZATION: 2009, pneumonia

Case history

Branden is a 28-year-old CGD patient. Within his first year of life, Branden exhibited failure to thrive and experienced recurrent pneumonia. Between ages 1 and 7 years, Branden experienced frequent staphylococcal infections in his fingers and continuing recurrent pneumonia, which eventually resulted in pleural effusion. He was tested for cystic fibrosis and dwarfism and underwent extensive allergy testing. In 1995, at age 7, Branden was diagnosed with CGD.

At diagnosis, Branden was prescribed trimethoprim-sulfamethoxazole and ACTIMMUNE®. In 2002, itraconazole was added to his treatment regimen. From 2003 to 2005, Branden experienced minimal infectious complications. In 2006, Branden was hospitalized for a staphylococcal infection in the lymph node. In 2009, during his sophomore year of college, he was hospitalized for pneumonia. Admittedly, Branden was not adherent to the 3x weekly ACTIMMUNE® dosing schedule during his college years; this was Branden’s experience, and experiences vary among patients.

Now, with consistent use of trimethoprim-sulfamethoxazole, itraconazole, and ACTIMMUNE®, Branden has not been hospitalized since 2009 and currently experiences only minor flu-like symptoms from his medication.

In a clinical trial of patients taking ACTIMMUNE® 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 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).

*Serious infection was defined as a clinical event requiring hospitalization and intravenous antibiotics.

Complete your CGD treatment plan

As part of a combination treatment regimen along with prophylaxis therapy, ACTIMMUNE® is recommended by the3-5:

- American Academy of Allergy, Asthma & Immunology
- American College of Allergy, Asthma & Immunology
- Immune Deficiency Foundation

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.
CGD medical history and treatment intervention

1988  Born/recurrent pneumonia
• Tested for cystic fibrosis

1989  Cellulitis (foot)
• Caused by insect bite
• 5-day hospitalization; treated with intravenous antibiotics

1990 to 1994  Recurrent pneumonia and staphylococcal infections (fingers)
• Tested for dwarfism
• Tested extensively for allergies

1995  Pneumonia
• Resulted in pleural effusion that was pressing on the heart; thoracentesis performed
• 2-week hospitalization

Diagnosed with CGD
• Started on ACTIMMUNE® and trimethoprim-sulfamethoxazole within 2 weeks of diagnosis

1996 to 2002  Hospitalized intermittently for pneumonia
• Typically treated out of hospital because of doctors’ responsiveness and aggressive approach
• When needed, hospital stays ranged from 2 to 3 days

2006  Staphylococcal infection (lymph node)
• Required incision, drainage, and 1-week hospital stay
• Received intravenous antibiotics from home for 2 additional weeks

2009  Pneumonia
• Thought to be caused by Aspergillus species
• 2-week hospitalization

“There were times in high school and college when I got tired of giving myself an injection 3 times a week and would skip doses. Finally, when I came down with pneumonia in college and was hospitalized for 2 weeks, I realized that 2 minutes out of my daily life to give myself a shot isn’t such a big deal. I’ve been adherent ever since.”

—BRANDEN

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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