

# **Patient Dose**

<b>Patient Name</b>			<b>Date of Administration</b>		/	/
	First	Last		MM	DD	YYYY

Starting ACTIMMUNE				
Calculating Your Patient's Dose	Dosage Results <sup>1,2</sup>			
The following information was used to calculate your patient's dose.	This is the calculated dose of ACTIMMUNE for your patient.			
Height Weight	mcg			
BSA <sup>a</sup> m <sup>2</sup>	per dose, administered 3x weekly			

<sup>&</sup>lt;sup>a</sup>BSA can be calculated by multiple methods; the Mosteller formula is used on this website.<sup>3</sup>

Connect with a <u>Horizon Representative</u> for assistance in calculating a dose for patients with BSA  $\leq 0.5 \text{ m}^2$ .

ACTIMMUNE is a sterile, clear, colorless solution filled in a single-use vial for subcutaneous injection. Each 0.5 mL of ACTIMMUNE contains 100 mcg (2 million International Units) of interferon gamma-1b.1\*

\*Note that the above activity is expressed in International Units (1 million International Units/50 mcg). This is equivalent to what was previously expressed as units (1.5 million units/50 mcg).

If severe reactions occur, the dose should be reduced by 50% or therapy interrupted until the adverse reaction abates.<sup>1</sup>

ACTIMMUNE should be administered subcutaneously 3 times weekly. 1,2 It can be injected by the patient or caregiver after appropriate training by a healthcare professional. 1

BSA, body surface area.

**References: 1.** ACTIMMUNE (Interferon gamma-1b) [prescribing information] Horizon. **2.** The International Chronic Granulomatous Disease Cooperative Study Group. A controlled trial of interferon gamma to prevent infection in chronic granulomatous disease. *N Engl J Med.* 1991;324(8):509-516. **3.** Mosteller RD. Simplified calculation of body-surface area. *N Engl J Med.* 1987;317(17):1098.

## Approved Uses and Important Safety Information

#### 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-1b, 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
  - Myelosuppression or receiving other potentially myelosuppressive agents
  - Severe renal insufficiency
  - Age <1 year</li>
- Monitoring:
  - Before starting ACTIMMUNE and every 3 months during treatment, hematologic tests, blood chemistries, and urinalysis are recommended for all patients
  - Patients begun on ACTIMMUNE before the age of 1 year should receive monthly assessments of liver function. If severe hepatic enzyme elevations develop, ACTIMMUNE dosage should be modified
  - o 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

#### **USE IN SPECIFIC POPULATIONS**

- ACTIMMUNE should be used during pregnancy only if the potential benefit to the patient outweighs the potential risk to the fetus
- It is not known if ACTIMMUNE is excreted in human milk, so either ACTIMMUNE or nursing should be discontinued dependent on the importance of the drug to the patient
- In younger patients, long-term effects of ACTIMMUNE on fertility are not known
- In animal studies, both male and female fertility was negatively impacted by doses significantly higher than the maximum clinical dose

#### 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

Please see <u>Full Prescribing Information</u> for complete safety information.



