Vaccinia Immune Globulin Intravenous (DynPort Vaccine Co.)

An immunoglobulin containing antivaccinia antibody for the treatment and/or modification of serious complications of smallpox vaccination, including eczema vaccinatum, progressive vaccinia, severe generalized vaccinia, and vaccinia infections in people who have skin conditions, such as burns, impetigo, or varicella zoster.

- **Recommended Dosage:** 2 mL/kg administered in an intravenous infusion.
- **Special Considerations:** Adverse effects in two studies of 111 healthy volunteers included headaches, hives, and other types of rashes, but were mild to moderate; over-all, vaccinia immune globulin intravenous (VIGIV) was well tolerated.
- **Comment:** Approval of VIGIV—derived from pooled plasma of donors who recovered from naturally acquired smallpox infections—may help minimize the risks of the smallpox vaccine, when used in cases where the vaccine’s benefits are thought to outweigh its risks, citing the example of responders to a bioterrorist attack.

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**References:**


**LIFETIDES**

**Dosing and Administration**

Initial dosage of 2 mL/kg in a single dose in an intravenous infusion. Follow-up doses may be administered at approximately every 2 weeks, as tolerated.

**Dosage Adjustments**

- **In the Can-desartan in Heart Failure Assessment of Re-duction in Mortality and Morbidity (CHARM) program, three trials comparing Atacand with placebo in HF populations, 4% of those on Atacand had to stop use of the drug because of hypotension, vs. 2% of those on placebo.**
- **Hyperkalemia leading to discontinuation occurred in 2.5% of those on Atacand and 0.6% of those on placebo. Patients must be monitored closely during titration because some develop renal insufficiency, hyperkalemia, or hypotension—side effects expected with any drug that affects the renal angiotensin system, said Christopher Granger, M.D., director of the cardiac care unit at Duke University, Durham, N.C.
- **Supporting the approval were results of one of the three CHARM trials, CHARM-Alternative, which enrolled 2,028 patients with symptomatic heart failure and a left ventricular ejection fraction of 40% or less, who were on standard HF treatments but were intolerant of ACE inhibitors. After a median follow-up of 34 months, the risk of cardiovascular death or hospitalization for HF, and made people feel better,” said Dr. Granger, who was on the executive committee for CHARM. He served as a consultant to AstraZeneca at the meeting of the FDA’s Cardiovascular and Renal Drugs Advisory Committee, which unanimously recommended approval of Atacand for use in patients on an ACE inhibitor. Adding Atacand to standard treatment, including a β-blocker, cut cardiovascular mortality by 15%, compared with those on placebo, a highly significant effect.

Supporting the approval were results of CHARM-Added, of more than 2,500 patients with NYHA class II-IV heart failure and ejection fractions of 40% or less, who were on standard HF treatments but were intolerant of ACE inhibitors. Being reviewed for use with an ACE inhibitor in treating HF, as backed by an FDA advisory panel last month.

**Special Considerations:** Adverse effects in two studies of 111 healthy volunteers included headaches, hives, and other types of rashes, but were mild to moderate; over-all, vaccinia immune globulin intravenous (VIGIV) was well tolerated.

- **Comment:** Approval of VIGIV—derived from pooled plasma of donors who recovered from naturally acquired smallpox infections—may help minimize the risks of the smallpox vaccine, when used in cases where the vaccine’s benefits are thought to outweigh its risks, citing the example of responders to a bioterrorist attack.

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**Atacand**

(candesartan, AstraZeneca) An angiotensin receptor blocker (ARB) for treating patients with chronic heart failure (NYHA class II-IV and an ejection fraction of 40% or less), to reduce the risk of death from cardiovascular causes and reduce hospitalizations for heart failure. The second ARB approved for heart failure (HF), the first was Diovan (valsartan), approved in 2002 for a narrower indication, NYHA class II-IV heart failure in people who cannot tolerate ACE inhibitors. Being reviewed for use with an ACE inhibitor in treating HF, as backed by an FDA advisory panel last month.

**Recommended Dosage:** Starting at 4 mg/day, with a target dose of 32 mg once daily, achieved by doubling the dose approximately every 2 weeks, as tolerated.

**Special Considerations:** The Can-desartan in Heart Failure Assessment of Re-duction in Mortality and Morbidity (CHARM) program, three trials comparing Atacand with placebo in HF populations, 4% of those on Atacand had to stop use of the drug because of hypotension, vs. 2% of those on placebo. Patients must be monitored closely during titration because some develop renal insufficiency, hyperkalemia, or hypotension—side effects expected with any drug that affects the renal angiotensin system, said Christopher Granger, M.D., director of the cardiac care unit at Duke University, Durham, N.C.

**Comment:** This approval reflects findings of one of the three CHARM trials, CHARM-Alternative, which enrolled 2,028 patients with symptomatic heart failure and a left ventricular ejection fraction of 40% or less, who were on standard HF treatments but were intolerant of ACE inhibitors. After a median follow-up of 34 months, the risk of cardiovascular death or hospitalization for HF, and made people feel better,” said Dr. Granger, who was on the executive committee for CHARM. He served as a consultant to AstraZeneca at the meeting of the FDA’s Cardiovascular and Renal Drugs Advisory Committee, which unanimously recommended approval of Atacand for use in patients on an ACE inhibitor. Adding Atacand to standard treatment, including a β-blocker, cut cardiovascular mortality by 15%, compared with those on placebo, a highly significant effect.

Supporting the approval were results of CHARM-Added, of more than 2,500 patients with NYHA class II-IV heart failure and ejection fractions of 40% or less, and on an ACE inhibitor in treating HF, as backed by an FDA advisory panel last month.