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by the Seton Network Medical Executive Committee.*

Drug Shortage Communication and Action Plan: Vitamin K Injection

Products affected:

- Vitamin K injection, contains benzyl alcohol, 1 mg/0.5 mL and 10 mg/1 mL amp
- Vitamin K injection, contains polysorbate 80 and propylene glycol, 1 mg/0.5 mL pre-filled syringe

Reason for shortage:

- Hospira has vitamin K injection on shortage due to manufacturing delays.

Expected resolution time:

- Hospira estimates a release date of mid-December 2011 for the 1 mg/0.5 mL ampoules and late-November 2011 for the 10 mg/1 mL ampoules.
- Amphastar/IMS has 1 mg/0.5 mL prefilled syringes on intermittent back order and is releasing product weekly.

Recommended alternatives/management:

- Oral vitamin K is not affected by this shortage and should be used whenever possible.
- The American College of Chest Physicians created guidelines for management of antithrombotic and thrombolytic therapy that include management of hypothermia due to warfarin and other vitamin K antagonists. Recommendations for warfarin reversal based on international normalized ratio (INR) and evidence of bleeding are as follows:
 - If INR is <5, with no significant bleeding, no vitamin K is required. Reduce or skip warfarin dose and monitor INR frequently.
 - If INR is >5 or <9, with no significant bleeding, low doses of vitamin K of 1 to 2.5 mg given orally may be needed. For more rapid reversal give vitamin K up to 5 mg orally. Repeat a low dose of vitamin K if INR is still high the next day. Reduce or skip warfarin dose and monitor INR frequently. The INR is expected to decrease to desired level within 24 hours.

- If INR is >9, with no significant bleeding, give higher doses of vitamin of 2.5 to 5 mg. The INR is expected to decrease within 24-48 hours.
- Patients with serious bleeds, regardless of extent of INR elevation, should receive vitamin K 10 mg intravenously supplemented by fresh frozen plasma (FFP), prothrombin complex concentrate (PCC), or recombinant factor VIIa. Repeat as necessary.
- Patients with life-threatening bleeds regardless of extent of INR elevation should receive fresh frozen plasma (FFP), prothrombin complex concentrate (PCC), or recombinant factor VIIa supplemented by vitamin K 10 mg intravenous. Repeat as necessary.

Inventory on hand:

- Vitamin K 1 mg/0.5 mL injection = 567 (approximately 2-3 weeks of inventory). Pharmacy continues to receive product intermittently.
- Vitamin K 10 mg/1 mL ampoule = 113 (approximately 1-2 weeks of inventory). Product not available.

Action plan:

- Reserve vitamin K 1 mg injection for neonatal and pediatric indications.
- Reserve vitamin K 10 mg injection for severe or life-threatening bleeds.
- Utilize oral therapy whenever possible.
- Remove all vitamin K from adult TPN. Reassess each patient after seven days on TPN and make specific recommendations at that time if vitamin K is needed.

Date action plan effective: Nov. 11, 2011

Next communication date: Nov. 21, 2011