http://www.ashp.org/menu/PracticePolicy/ResourceCenters/DrugShortages/CurrentShortages.aspx

Atropine Sulfate Injection

[10 April 2012]

Products Affected - Description

Atropine injection, Hospira
0.05 mg/mL, 5 mL Ansyr syringe, package of 10 (NDC 00409-9630-05)
0.1 mg/mL, 5 mL Lifeshield syringe, package of 10 (NDC 00409-4910-34)

Atropine injection, American Regent
0.4 mg/mL, 0.5 mL ampule, package of 25 (NDC 00517-0805-25) - *discontinued*
0.4 mg/mL, 1 mL single-dose vial, package of 25 (NDC 00517-0401-25)
1 mg/mL, 1 mL single-dose vial, package of 25 (NDC 00517-1010-25)
1 mg/mL, 1 mL ampule, package of 25 (NDC 00517-0101-25)- *discontinued*

Atropine injection, West-Ward (formerly Baxter)
0.4 mg/mL, 1 mL single-dose vial, package of 25 (NDC 10019-0250-12)
0.4 mg/mL, 20 mL multi-dose vial, package of 10 (NDC 10019-0250-20) - *NDC discontinued*
1 mg/mL, 1 mL single-dose vial, package of 25 (NDC 10019-0251-12)

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira states the shortage is due to manufacturing delays.
- West-Ward acquired Baxter's atropine injection products in May, 2011. NDC codes began changing for these products in early, 2012.

Available Products

Atropine injection, Amphastar
0.1 mg/mL, 10 mL Luer-Jet syringes (NDC 00548-3339-00)

Atropine injection, Hospira
0.1 mg/mL, 10 mL Lifeshield 21 gauge syringe, package of 10 (NDC 00409-4911-34)
0.1 mg/mL, 10 mL Ansyr syringe, package of 10 (NDC 00409-1630-10)

Atropine injection, West-Ward
0.4 mg/mL, 20 mL multi-dose vial, package of 10 (NDC 00641-6006-10)

Estimated Resupply Dates

- Hospira has atropine 0.05 mg/mL 5 mL Ansyr syringes on back order and the company estimates a release date of April, 2012. The atropine 0.1 mg/mL 5 mL Lifeshield syringes are on back order and the company estimates a release date of late-April, 2012.
- American Regent has all atropine 0.4 mg/mL and 1 mg/mL presentations on back order and the company cannot estimate a release date.
- West-Ward has atropine 0.4 mg/mL 1 mL vials and atropine 1 mg/mL 1 mL vials on back order and the company cannot estimate a release date.

Diazepam Injection

[11 April 2012]

Products Affected - Description

Diazepam injection 5 mg/mL, Hospira
2 mL Carpuject Luer-Lock syringes, package of 10 (NDC 00409-1273-32)
2 mL iSecure syringes, package of 10 (NDC 00409-1273-05)
10 mL vials, package of 10 (NDC 00409-3213-12)

Reason for the Shortage

- Hospira has diazepam on back order due to manufacturing delays.[1]
- Hospira is the sole supplier of diazepam injection.

Available Products

There are no presentations readily available.

Estimated Resupply Dates

Hospira has diazepam 5 mg/mL 2 mL Carpuject syringes available in limited supply. The 10 mL vials are on back order and the company estimates a release date of late-April, 2012. The 2 mL iSecure syringes are on back order and the company cannot estimate a release date.

Implications for Patient Care

Diazepam injection is labeled for treating anxiety disorders (short-term), alcohol withdrawal symptoms, status epilepticus and severe recurrent seizures, and skeletal muscle spasms associated local pathology, upper motor neuron disorders, athetosis, tetanus, or stiff-man syndrome. Diazepam injection is also labeled as an adjunct prior to endoscopic procedures and as premedication prior to surgical procedures or cardioversion.

Off-label uses of diazepam injection include sedation in the critical care setting for patients on mechanical ventilation, reduction of opioid requirements and production of amnesia in labor and delivery, management neonatal opiate withdrawal, and treatment of tardive dyskinesia.

Alternative Agents & Management

- During this shortage use alternative injectable benzodiazepines or agents from another pharmacologic class as appropriate for the indication.
- There are no direct dosage conversions between the benzodiazepines because each has a distinct pharmacokinetic profile that dictates the agent's therapeutic use and dosing. The Table compares the pharmacokinetics of injectable benzodiazepines.
- Lorazepam and midazolam injection are also on shortage.
- Institutions may consider reserving injectable benzodiazepines for initial treatment of status epilepticus, as no other well established injectable therapeutic options are available for this indication. Diazepam rectal gel may be an alternative for some patients.

Table. Pharmacokinetics of Injectable Benzodiazepines[2-4,11-13]

Agent	Onset of Action (min)		Duration of Action (hours)		Half-life (hours)	Active Metabolites
	Intravenous	Intramuscular	Intravenous	Intramuscular		
Diazepam	1–5	[a]	0.3–0.5	[a]	20–120	Yes
Lorazepam	5–20	15–30	6–8	6–8	8–15	No
Midazolam	1–5	5–15	≤2[b]	2[b]	3–11	Yes

[a] Intramuscular administration results in slow and erratic absorption.
[b] The pharmacologic effect of midazolam may last up to 6 hours in some patients.

Diphenhydramine Hydrochloride for Injection

[29 March 2012]

Products Affected - Description

Diphenhydramine injection, 50 mg/mL, Hospira
1 mL Carpuject syringe (NDC 00409-2290-31)

Diphenhydramine injection, 50 mg/mL, Mylan Institutional
10 mL vial (NDC 67457-0124-10)

Reason for the Shortage

- Mylan Institutional has diphenhydramine injection on shortage due to increased demand. The company is increasing production to try to meet this demand.
- Hospira discontinued diphenhydramine iSecure syringes in 2011.
- West-Ward could not provide a reason for the shortage.
- Pfizer discontinued all Benadryl injection in 2005.
- IMS discontinued diphenhydramine injection in April 2008.

Available Products

Diphenhydramine injection, 50 mg/mL, APP
1 mL vial (NDC 63323-0664-01)

Diphenhydramine injection, 50 mg/mL, West-Ward (formerly Baxter products)
1 mL vial (NDC 00641-0376-25)

Estimated Resupply Dates

- Hospira has diphenhydramine injection 1 mL Carpuject on back order and the company estimates a release date of June, 2012.
- Mylan Institutional has diphenhydramine 50 mg/mL 10 mL vials on back order with an estimated release date of mid-April, 2012.

Dopamine Injection

[04 April 2012]

Products Affected - Description

Dopamine in Dextrose 5% Injection, Hospira
200 mg/250 mL (NDC 00409-7808-22)
400 mg/500 mL (NDC 00409-7808-24)
400 mg/250 mL (NDC 00409-7809-22)
800 mg/500 mL (NDC 00409-7809-24)
800 mg/250 mL (NDC 00409-7810-22)

Dopamine Injection, Hospira
40 mg/mL, 5 mL vial (NDC 00409-5820-01)

Reason for the Shortage

- Baxter could not provide a reason for the shortage.
- B Braun states the shortage was due to increased demand.
- Hospira states the shortage is due to manufacturing delays.
- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Available Products

Dopamine injection, American Regent
40 mg/mL, 5 mL vial (NDC 00517-1805-25)
80 mg/mL, 5 mL vial (NDC 00517-1905-25)
160 mg/mL, 5 mL vial (NDC 00517-1305-25)

Dopamine in Dextrose 5% Injection, Baxter
200 mg/250 mL (NDC 00338-1005-02)
400 mg/250 mL (NDC 00338-1007-02)
400 mg/500 mL (NDC 00338-1005-03)
800 mg/250 mL (NDC 00338-1009-02)
800 mg/500 mL (NDC 00338-1007-03)

Dopamine in Dextrose 5% Injection, B Braun
400 mg/250 mL (NDC 00264-1482-55)

Dopamine Injection, Hospira
40 mg/mL, 10 mL vial (NDC 00409-9104-20)

Estimated Resupply Dates

- Hospira has limited supplies of dopamine 200 mg/250 mL, 400 mg/250 mL, and 400 mg/500 mL premixes. Dopamine 800 mg/250 mL premixes are on back order with an estimated release date of April, 2012. Dopamine 800 mg/500 mL premixes on back order with an estimated release date of June, 2012.
- Hospira has dopamine 40 mg/mL 5 mL vials on intermittent back order and the company is releasing product as it becomes available.

Epinephrine Injection

[27 March 2012]

Products Affected - Description

Epinephrine injection, 1 mg/mL, American Regent
1 mL ampule, sulfite-free, package of 25 (NDC 00517-1071-25)

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Available Products

Epinephrine injection, 1 mg/mL, American Regent
30 mL multi-dose vial, package of 5 (NDC 00517-1130-05)

Epinephrine injection, 1 mg/mL, Amphastar
30 mL vial (NDC 00548-9061-00)

Epinephrine injection, 1 mg/mL, Hospira
1 mL ampule, preservative-free (contains sulfite), package of 25 (NDC 00409-7241-01)

Adrenalin injection, 1 mg/mL, JHP
1 mL vial, preservative-free (contains sulfite), package of 25 (NDC 42023-0122-25)
30 mL multi-dose vial, package of 1 (NDC 42023-0101-01)
30 mL multi-dose vial, package of 10 (NDC 42023-0101-10)

Estimated Resupply Dates

American Regent has epinephrine 1 mg/mL preservative free (sulfite-free) 1 mL ampules on back order and the company cannot estimate a release date. Limited supplies may be available from wholesalers.

Fentanyl Injection

[13 April 2012]

Products Affected - Description

Fentanyl Injection 50 mcg/mL, Hospira
10 mL ampules (NDC 00409-9093-36) - *discontinued*
2 mL ampule (NDC 00409-9093-32)
5 mL ampule (NDC 00409-9093-35)
20 mL ampule (NDC 00409-9093-38)
2 mL vial (NDC 00409-9094-22)
5 mL vial (NDC 00409-9094-25)
10 mL vial (NDC 00409-9094-28)
20 mL vial (NDC 00409-9094-31)
50 mL vial (NDC 00409-9094-61)

Fentanyl Injection 50 mcg/mL, West-Ward (formerly Baxter products)
10 mL ampule (NDC 10019-0034-73) - *discontinued*
30 mL single-dose vial (NDC 10019-0036-82) - *discontinued*
2 mL ampule (NDC 10019-0038-67)
2 mL vial (NDC 10019-0037-27)
50 mL vial (NDC 10019-0037-83)
5 mL ampule (NDC 10019-0033-72)
5 mL vial (NDC 10019-0037-30)
20 mL vial (NDC 10019-0037-25)

Reason for the Shortage

- West-Ward acquired Baxter's fentanyl injection products in May, 2011. The company cannot provide a reason for the shortage.[1,2]
- Hospira states the shortage is due to increased demand and manufacturing delays including quality improvement activities. Hospira is increasing production of the ampules to help meet the demand. [3]
- Akorn launched Sublimaze injection in late-March, 2012.[4]

Available Products

Sublimaze Injection 50 mcg/mL, Akorn
2 mL ampules (NDC 17478-0030-02)
5 mL ampules (NDC 17478-0030-05)
10 mL ampules (NDC 17478-0030-20)

Fentanyl Injection 50 mcg/mL, Hospira
2 mL Carpuject syringe (NDC 00409-1276-32)

Fentanyl Injection 50 mcg/mL, West-Ward (formerly Baxter products)
20 mL ampule (NDC 10019-0035-74)

Estimated Resupply Dates

- Hospira has fentanyl 50 mcg/mL 2 mL, 5 mL, 10 mL, 20 mL, and 50 mL vials on back order and the company estimates a release date of May, 2012. The 2 mL and 5 mL ampules are on intermittent back order and the company is releasing product as it becomes available.[3]
- West-Ward has most fentanyl 50 mcg/mL injections on intermittent back order and the company is releasing product as it becomes available except the 5 mL vials have an estimated release date of early-May, 2012 and the 20 mL vials do not have an estimated release date. The 20 mL ampules are available.[1]

Implications for Patient Care

Fentanyl is labeled for use in analgesia for short duration or as a narcotic supplement in general and regional analgesia.[5] Fentanyl is also labeled for use with a neuroleptic for premedication of induction of anesthesia and as an adjunct for general anesthesia maintenance. Fentanyl is also labeled for use with oxygen as an anesthetic agent in high risk patients, including those undergoing complicated procedures.[5]

Safety

Remifentanil, alfentanil, fentanyl and sufentanil may sound alike/look alike. However, dosage recommendations vary significantly between the agents.[5-8]
Patient harm can occur if these agents are used erroneously. Use extra caution not to confuse these agents.

Alternative Agents & Management

- Alternative opiate agonists vary in onset time and duration of action, see Table 1.[5-15]
- No single agent can be substituted for fentanyl. The choice of an alternative agent must be patient-specific and based on the clinical situation, venous access, renal and hepatic function, and other comorbid conditions. Utilize stakeholder clinicians to help make specific plans for individual patient populations. Table 2 provides some alternatives to fentanyl for specific clinical situations.
- Some presentations of alternative agents including sufentanil and butorphanol are in short supply.[16]
- Drawing up individual doses in syringes may help conserve product. Ensure USP 797 requirements are met.
- Consider reserving fentanyl for high risk populations such as newborn and obstetrics.

Furosemide Injection

[11 April 2012]

Products Affected - Description

Furosemide Injection, 10 mg/mL, Hospira
2 mL vial (NDC 00409-6102-02)
4 mL vial (NDC 00409-6102-04)
2 mL Carpuject syringe (NDC 00409-1275-32) - *discontinued*
10 mL syringe (NDC 00409-6102-10)

Furosemide Injection, 10 mg/mL, American Regent
2 mL vial (NDC 00517-5702-25)
4 mL vial (NDC 00517-5704-25)
10 mL vial (NDC 00517-5710-25)

Furosemide Injection, 10 mg/mL, APP[1]
2 mL vial (NDC 63323-0280-02)
4 mL vial (NDC 63323-0280-04)
10 mL vial (NDC 63323-0280-10)

Reason for the Shortage

- APP has furosemide injection on shortage due to increased demand for the product.
- American Regent had temporarily suspended manufacture of most drug products including furosemide in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira has furosemide on shortage due to manufacturing delays.
- Wockhardt has discontinued all furosemide injection presentations.

Available Products

Furosemide Injection, 10 mg/mL, Hospira[5]
10 mL Luer lock syringe (NDC 00409-1639-10)
4 mL syringe (NDC 00409-9631-04)

Estimated Resupply Dates

- American Regent has furosemide 10 mg/mL 2 mL, 4 mL, and 10 mL vials on back order and the company cannot estimate a release date. Limited supply may be available at wholesalers of the 2 mL and 4 mL vials.[3]
- APP has all furosemide 10 mg/mL injection on allocation and product is short-dated.[1]
- Hospira has furosemide 10 mg/mL 4 mL vials and 10 mL syringes on intermittent back order and the company is releasing product as it becomes available. The 2 mL vials are on back order and the company estimates a release date of June, 2012. Limited supply may be available of the 2 mL and 4 mL vials.[5]

Implications for Patient Care

Furosemide injection is indicated in the adjunctive treatment of acute pulmonary edema; edema associated with congestive heart failure and hepatic cirrhosis; edema caused by renal diseases including nephrotic syndrome, acute glomerulonephritis, and chronic renal failure; and hypertension, either as a single agent or in combination with other antihypertensives.[7-9] The preferred route of administration of furosemide is oral, although the injection may be administered when a rapid onset of action is required, or when patients cannot take oral medications.[7-9]

Safety

- Loop diuretics can cause water and electrolyte imbalances from potent diuresis and individualized dosing and supervision is recommended.[7-12]
- Patients who are allergic to sulfonamides are at risk for a cross-reaction with sulfonamide-type diuretics and should not receive these agents except for ethacrynic acid.[7-12]

Alternative Agents & Management

During this shortage, use oral loop diuretics when possible. Furosemide is available as an oral liquid if tablets are not tolerated. Furosemide is the only loop diuretic available in an oral liquid presentation.[7-12] Several injectable loop diuretics are available when oral furosemide is not a viable option. Table 1 compares the pharmacodynamics of and Table 2 provides information on dosages for injectable loop diuretics.

Table 2. Dosage regimens of injectable loop diuretics[7-12]

Drug	Usual Adult Dosage	Comments
Furosemide	Edema, initial dose: 20-40 mg/dose IV or IM every 2 hours as needed. Increase the dose by 20 mg every 2 hours until desired effects are seen. Edema, maintenance dosage: Give the effective dose once or twice daily. Up to 4 grams/day in patients with congestive heart failure and 6 grams/day in patients with chronic renal failure is being investigated. Acute pulmonary edema: 40 mg IV. After 1 hour, may increase the dose to 80 mg if diuretic response is inadequate. Continuous infusion: 20-40 mg bolus IV, followed by 10-40 mg/hour. Double the rate every 2 hours, up to a maximum 80-160 mg/hour.	Administer small doses (20-80 mg) IV over 1-2 min. Administer large doses (1 gram) IV over 30 min. Avoid use in patients with oliguria. Rates up to 4 mg/minute have been used.
Bumetanide	Edema, initial dose: 0.5-1 mg IV or IM. Repeat in 2-3 hours if response is inadequate, up to a maximum of 10 mg/day. Edema, maintenance dose: give the effective dose (from titration) intermittently as needed.	Administer IV over 1-2 minutes. Risk of cross-reactivity in patients with furosemide allergy is low (1:40); bumetanide may be a good choice in these patients.
Torsemide	10-20 mg IV once daily. Double the dose (maximum of 200 mg/dose) until desired therapeutic response is achieved. Hepatic cirrhosis: 5-10 mg IV once daily. Double the dose (maximum of 40 mg/dose) until desired therapeutic response is achieved.	Administer IV over 2 minutes. Extensively metabolized in the liver; dosage may need adjustment in patients with hepatic impairment.
Ethacrynic acid	Edema, initial dose: 50 mg IV or 0.5-1 mg/kg (up to 100 mg/dose). Usually only a single dose is necessary; may repeat in 2-4 hours if additional diuresis is needed. Edema, maintenance dose: Give the effective dose every 8-12 hours.	Administer IV over several minutes. Causes pain and irritation at the injection site; do not inject IM or SC. If a second dose is needed, use a new injection site to reduce the risk of thrombophlebitis. Has higher risk than other loop diuretics of causing ototoxicity. Avoid use in patients with a creatinine clearance of< 10 mL/minute.

Abbreviations: IM = intramuscular; IV = intravenous; SC = subcutaneous

Lorazepam injectable presentations

[20 April 2012]

Products Affected - Description

Lorazepam 2 mg/mL, Akorn
1 mL vial (NDC 17478-0040-01)

Lorazepam 2 mg/mL, Bedford
1 mL vial (NDC 55390-0168-10) - *discontinued*
10 mL vial (NDC 55390-0170-10) - *discontinued*

Lorazepam 4 mg/mL, Bedford

1 mL vial (NDC 53390-0169-10) - *discontinued*
10 mL vial (NDC 53390-0171-10) - *discontinued*

Lorazepam 2 mg/mL, Hospira
1 mL iSecure prefilled syringes (NDC 00409-1985-05) - *discontinued*
1 mL Carpuject syringes (NDC 00409-1985-30)
1 mL vial (NDC 00409-6778-02)
10 mL vials (NDC 00409-6780-02)

Lorazepam 4 mg/mL, Hospira
1 mL vial (NDC 00409-6779-02)
10 mL vial (NDC 00409-6781-02)
1 mL Carpuject syringes (NDC 00409-1539-31)

Lorazepam 2 mg/mL, West-Ward
10 mL vial (NDC 00641-6046-10)
1 mL Novaplus vial (NDC 00641-6048-25)
10 mL Novaplus vial (NDC 00641-6050-10)
1 mL vial (NDC 10019-0102-01) - *discontinued*
10 mL vial (NDC 10019-0102-10) - *discontinued*
1 mL Novaplus vial (NDC 10019-0105-01) - *discontinued*
10 mL Novaplus vial (NDC 10019-0105-02) - *discontinued*

Ativan 2 mg/mL, West-Ward
1 mL vial (NDC 00641-6001-25)
10 mL vial (NDC 00641-6000-10)
1 mL vial (NDC 60977-0112-01) - *discontinued*
10 mL vial (NDC 60977-0116-02) - *discontinued*

Lorazepam 4 mg/mL, West-Ward
1 mL vial (NDC 00641-6045-25)
1 mL Novaplus vial (NDC 00641-6049-25)
10 mL vial (NDC 00641-6047-10)
10 mL Novaplus vial (NDC 00641-6051-10)
1 mL vial (NDC 10019-0103-01) - *discontinued*
1 mL Novaplus vial (NDC 10019-0106-01) - *discontinued*
10 mL vial (NDC 10019-0103-10) - *discontinued*
10 mL Novaplus vial (NDC 10019-0106-02) - *discontinued*

Ativan 4 mg/mL, West-Ward
1 mL vial (NDC 00641-6003-25)
10 mL vial (NDC 00641-6002-10)
1 mL vial (NDC 60977-0113-01) - *discontinued*
10 mL vial (NDC 60977-0113-02) - *discontinued*

Reason for the Shortage

- Bedford discontinued lorazepam in May, 2011 to concentrate on the manufacturing of other products.
- West-Ward acquired Baxter's lorazepam injection products in May, 2011. NDC numbers for the lorazepam and Ativan products were changed in April, 2012. The company cannot provide a reason for the shortage.
- Hospira states lorazepam vials are on shortage due to increased demand. The 1 mL iSecure syringes were discontinued in September 2011.
- Akorn has increased production to help meet demand.

Available Products

Lorazepam 2 mg/mL, West-Ward
1 mL vial (NDC 00641-6044-25)

Estimated Resupply Dates

- West-Ward has lorazepam and Ativan injection on back order with an estimated release date of late-April to early-May, 2012.[2]
- Hospira has all lorazepam presentations on back order. The 4 mg/mL 1 mL Carpuject syringes have an estimated release date of 2013. Lorazepam 2 mg/mL 1 mL vials and 4 mg/mL 1 mL vials have an estimated release date of June, 2012. Lorazepam 2 mg/mL 10 mL vials and 4 mg/mL 10 mL vials have an estimated release date of May, 2012. Lorazepam 2 mg/mL 1 mL Carpuject syringes have an estimated release date of late-April, 2012.
- Akorn is allocating lorazepam 2 mg/mL 1 mL vials.

Implications for Patient Care

Lorazepam injection is labeled for treatment of status epilepticus and as premedication for the relief of anxiety and tension in patients undergoing surgical procedures. Off-label uses of lorazepam injection include sedation in the critical care setting for patients on mechanical ventilation, treatment of acute delirium, and adjunctive treatment of chemotherapy induced nausea and vomiting.

Alternative Agents & Management

- During this shortage, use alternative injectable benzodiazepines.
- There are no direct dosage conversions between the benzodiazepines because each has a distinct pharmacokinetic profile that dictates the agent's therapeutic use and dosing. The table below compares the pharmacokinetics of injectable benzodiazepines.
- Institutions may consider reserving injectable benzodiazepines for initial treatment of status epilepticus, as no other well established injectable therapeutic options are available for this indication. Diazepam rectal gel may be an alternative for some patients.

Table. Pharmacokinetics of Injectable Benzodiazepines

Agent	Onset of Action (min)		Duration of Action (hours)		Half-life (hours)	Active Metabolites
	Intravenous	Intramuscular	Intravenous	Intramuscular		
Diazepam	1-5	[a]	0.3-0.5	[a]	20-120	Yes
Lorazepam	5-20	15-30	6-8	6-8	8-15	No
Midazolam	1-5	5-15	$\leq$2[b]	2[b]	3-11	Yes

[a] Intramuscular administration results in slow and erratic absorption.
[b] The pharmacologic effect of midazolam may last up to 6 hours in some patients.

Midazolam Injections

[10 April 2012]

Products Affected - Description

Midazolam Injection, APP
1 mg/mL, 2 mL vial, 25 count (NDC 63323-0411-12)

1 mg/mL, 5 mL vial, 25 count (NDC 63323-0411-25)
1 mg/mL, 10 mL vial, 10 count (NDC 63323-0411-10)
5 mg/mL, 5 mL vial, 10 count (NDC 63323-0412-05)
5 mg/mL, 10 mL vial, 10 count (NDC 63323-0412-10)
5 mg/mL, 2 mL vial, 25 count (NDC 63323-0412-02)
5 mg/mL, 1 mL fill in 2 mL vial, 25 count (NDC 63323-0412-25)

Midazolam Injection, Bedford
1 mg/mL, 2 mL preservative-free vial, 10 count (NDC 55390-0137-02)
1 mg/mL, 5 mL preservative-free vial, 10 count (NDC 55390-0137-05)
1 mg/mL, 10 mL vial, 10 count (NDC 55390-0125-10)
5 mg/mL, 2 mL preservative-free vial, 10 count (NDC 55390-0138-02)
5 mg/mL, 1 mL preservative-free, in 2 mL vial, 10 count (NDC 55390-0138-01)
5 mg/mL, 5 mL vial, 10 count (NDC 55390-0126-05)
5 mg/mL, 10 mL vial, 10 count (NDC 55390-0126-10)

Midazolam Injection, Hospira
1 mg/mL, 2 mL preservative-free Luer-lock syringe (NDC 00409-2306-62)
1 mg/mL, 2 mL preservative-free vial (NDC 00409-2305-17)
1 mg/mL, 2 mL Novaplus preservative-free vial, 100 count (NDC 00409-2305-21)
1 mg/mL, 5 mL preservative-free vial, 10 count (NDC 00409-2305-05)
1 mg/mL Novaplus 5 mL preservative-free vial (NDC 00409-2305-50)
1 mg/mL, 2 mL preservative-free iSecure syringe (NDC 00409-2306-12)
1 mg/mL Novaplus 10 mL vial (NDC 00409-2587-53)
1 mg/mL, 10 mL vial (NDC 00409-2587-05)
5 mg/mL, 1 mL preservative-free vial (NDC 00409-2308-01)
5 mg/mL, 1 mL preservative-free Novaplus vial (NDC 00409-2308-49)
5 mg/mL, 5 mL vial, 10 count (NDC 00409-2596-03)
5 mg/mL, 10 mL vial, 10 count (NDC 00409-2596-05)
5 mg/mL, 1 mL preservative-free Luer-Lock syringe, 10 count (NDC 00409-2307-60)
5 mg/mL, 2 mL preservative-free vial, 10 count (NDC 00409-2308-02)
5 mg/mL, 2 mL preservative-free Novaplus vial (NDC 00409-2308-50)
5 mg/mL, Novaplus 10 mL vial (NDC 00409-2596-53)
5 mg/mL, Novaplus 5 mL vial (NDC 00409-2596-52)

Midazolam Injection, Sagent
1 mg/mL, 2 mL preservative-free vial (NDC 25021-0655-02)
1 mg/mL, 5 mL preservative-free vial (NDC 25021-0655-05)
5 mg/mL, 1 mL preservative-free vial (NDC 25021-0656-01)
5 mg/mL, 2 mL preservative-free vial (NDC 25021-0656-02)
1 mg/mL, 10 mL vial (NDC 25021-0660-10)
5 mg/mL, 5 mL vial (NDC 25021-0661-05)
5 mg/mL, 10 mL vial (NDC 25021-0661-10)

Midazolam Injection, West-Ward (formerly Baxter products)
1 mg/mL, 2 mL vial, 10 count (NDC 10019-0028-02) - *discontinued*
1 mg/mL, 2 mL dosette vial (NDC 10019-0028-03) - *discontinued*
1 mg/mL, 5 mL vial, 10 count (new NDC 00641-6059-10, old NDC 10019-0028-05)
1 mg/mL, 10 mL vial, 10 count (new NDC 00641-6056-10, old NDC 10019-0028-10)
1 mg/mL, 2 mL vial, 25 count (new NDC 00641-6057-25, old NDC 10019-0028-04)
1 mg/mL, 2 mL latex free vial, 10 count (new NDC 00641-6057-10, old NDC 10019-0028-01)
5 mg/mL, 1 mL vial, 10 count (new NDC 00641-6061-10, old NDC 10019-0027-06)
5 mg/mL, 1 mL vial, 25 count (new NDC 00641-6061-25, old NDC 10019-0027-09)
5 mg/mL, 2 mL vial, 25 count (new NDC 00641-6063-25, old NDC 10019-0027-08)
5 mg/mL, 2 mL vial, 10 count (new NDC 00641-6063-10, old NDC 10019-0027-07)
5 mg/mL 10 mL vial, 10 count (new NDC 00641-6060-10, old NDC 10019-0027-10)

Reason for the Shortage

- West-Ward acquired Baxter's midazolam injection products in May, 2011. NDC codes began changing for these products in early, 2012.[1]
- Ben Venue voluntarily suspended all manufacturing and distribution in mid-November, 2011 on a temporary basis for maintenance and requalification of equipment. Product will become available in stages as production resumes.
- Bedford Laboratories has temporarily suspended the distribution of Ben Venue Laboratories manufactured products.[2] Availability of products is updated on the Bedford Laboratories website.
- Hospira has midazolam on shortage due to manufacturing delays and demand exceeding supply due to current market conditions.[3]
- Hospira discontinued midazolam 5 mg/mL 1 mL iSecure syringes in July 2011.[3]
- APP has midazolam on shortage due to increased demand.[4]

Available Products

No presentations are fully available.

Estimated Resupply Dates

- APP has midazolam injection on intermittent back order and the company is releasing product on a regular basis. Check with wholesalers for inventory.[4]
- Hospira has all midazolam injection on intermittent back order and the company is releasing product as it becomes available except for the 5 mg/mL preservative-free 1 mL Luer-lock syringes are expected in 2013.[3]
- Bedford has all midazolam presentations on back order and the company cannot estimate a release date. The 1 mg/mL 2 mL and 10 mL vials and the 5 mg/mL 2 mL (1 mL fill), 5 mL and 10 mL vials vials are pending release while the other presentations will not be manufactured until capacity permits.[2]
- Sagent has all midazolam presentations on allocation.[5]
- West-Ward has midazolam injection 1 mg/mL 5 mL vials and 5 mg/mL 10 mL vials on back order and the company estimates a release date of early-April, 2012. All other presentations have an estimated release date of late-April, 2012.[1]

Implications for Patient Care

Midazolam injection is labeled as monotherapy or combination therapy for sedation, amnesia, relief of anxiety and induction of anesthesia in patients undergoing surgery or diagnostic, therapeutic, or endoscopic procedures. Midazolam administered by continuous infusion is labeled for sedation in patients requiring mechanical ventilation.

Midazolam is also available as 2 mg/mL oral syrup. Midazolam oral syrup is labeled for relief of anxiety, sedation, and amnesia prior to induction of anesthesia or endoscopic, diagnostic, or therapeutic procedures in pediatric patients. Midazolam oral syrup is not labeled for use in adults.

Alternative Agents & Management

- During this shortage, use alternative injectable benzodiazepines.
- Consider midazolam oral syrup for pediatric patients. Typical doses of oral midazolam range from 0.25 mg/kg to 1 mg/kg in children 6 months to 15 years old. The onset of action following oral administration is 10 to 20 minutes.
- Ravitskiy et al[8] evaluated midazolam 2 mg/mL oral syrup for the treatment of perioperative anxiety in healthy adults undergoing Mohs surgery. Midazolam 10 mg oral syrup was safe and effective in this study.[8] Data evaluating midazolam oral syrup for use in adults in other settings are lacking.
- There are no direct dosage conversions between the benzodiazepines because each has a distinct pharmacokinetic profile dictating the agent's therapeutic use and dosing.
- Lorazepam and diazepam injection are also on shortage.

- Institutions may consider reserving injectable benzodiazepines for initial treatment of status epilepticus, as no other well established injectable therapeutic options are available for this indication. Diazepam rectal gel may be an alternative for some patients.

Morphine Injections

[20 April 2012]

Products Affected - Description

Astramorph (preservative-free) injection, APP
0.5 mg/mL 2 mL ampule, 10 count (NDC 63323-0291-80)
0.5 mg/mL 10 mL vial, 5 count (NDC 63323-0291-10)
1 mg/mL 2 mL ampule, 10 count (NDC 63323-0292-80)
1 mg/mL, 10 mL vial (NDC 63323-0292-10)

Morphine injection, West-Ward
10 mg/mL, 1 mL vial (NDC 00641-6070-25)
5 mg/mL, 1 mL vial (NDC 10019-0176-44) - *NDC discontinued*
10 mg/mL, 1 mL vial (NDC 10019-0178-44) - *NDC discontinued*
8 mg/mL, 1 mL vial (NDC 10019-0177-44) - *NDC discontinued*
10 mg/mL, 10 mL vial (NDC 10019-0178-62) - *NDC discontinued*
15 mg/mL, 1 mL vial (NDC 10019-0179-44) - *NDC discontinued*
15 mg/mL, 20 mL vial (NDC 10019-0179-63) - *NDC discontinued*
8 mg/mL, 1 mL ampule (NDC 10019-0177-68) - *discontinued*
10 mg/mL, 1 mL ampule (NDC 10019-0178-68) - *discontinued*

Duramorph (preservative-free), West-Ward
0.5 mg/mL, 10 mL ampules (NDC 60977-0016-02)
1 mg/mL, 10 mL ampules (NDC 60977-0017-01)

Infumorph (preservative-free), West-Ward
10 mg/mL, 20 mL ampule (NDC 60977-0114-01)
25 mg/mL, 20 mL ampule (NDC 60977-0115-01)

Morphine injection, Hospira
1 mg/mL 10 mL amp, package of 5 (NDC 00409-4058-21) - *discontinued*
0.5 mg/mL 10 mL, preservative-free vial (NDC 00409-3814-12)
1 mg/mL, 30 mL PCA vial (NDC 00409-2029-02)
2 mg/mL, 1 mL Carpuject syringe (NDC 00409-1762-30)
4 mg/mL, 1 mL Carpuject syringe (NDC 00409-1258-30)
5 mg/mL, 30 mL PCA vial (NDC 00409-6028-04)
8 mg/mL, 1 mL Carpuject syringes (NDC 00409-1260-69)
10 mg/mL, 1 mL Carpuject syringes (NDC 00409-1261-30)
25 mg/mL, 1 mL preservative-free vial (NDC 00409-1135-02)
50 mg/mL, 20 mL vial (NDC 00409-1134-03)
15 mg/mL, 1 mL Carpuject syringes (NDC 00409-1264-31)

Morphine Injection, IMS (Amphastar)
1 mg/mL, 10 mL Luer-lock syringes (NDC 00548-3391-00) - *discontinued*

Reason for the Shortage

- APP states the shortage is due to a change in manufacturing sites.

- Hospira states the shortage is due to manufacturing delays.
- West-Ward states the shortage is due to increased demand for product. West-Ward has recently changed old Baxter to new West-Ward NDC codes.
- IMS (Amphastar) discontinued morphine 1 mg/mL 10 mL Luer-lock syringes in March, 2012 due to low demand for the product.

Available Products

Morphine Injection, Hospira
1 mg/mL 10 mL preservative-free vial (NDC 00409-3815-12)
25 mg/mL 4 mL Add-Vantage vial (NDC 00409-6177-14)
25 mg/mL, 10 mL Add-Vantage vial (NDC 00409-6179-14)
50 mg/mL, 50 mL vial (NDC 00409-1134-05)

Morphine injection, West-Ward
5 mg/mL, 1 mL vial (NDC 00641-6073-25)
8 mg/mL, 1 mL vial (NDC 00641-6075-25)
10 mg/mL, 10 mL vial (NDC 00641-6068-01)
15 mg/mL, 1 mL vial (NDC 00641-6071-25)
15 mg/mL, 20 mL vial (NDC 00641-6072-01)

Estimated Resupply Dates

- APP has preservative-free Astramorph 0.5 mg/mL 2 mL ampules, 1 mg/mL 2 mL ampules and 10 mL ampules, and 0.5 mg/mL 10 mL vials on back order with an estimated release date in fourth quarter of 2012.
- West-Ward has morphine 10 mg/mL 1 mL vials on back order with an estimated release date of late-April to early-May, 2012. Duramorph 0.5 mg/mL and 1 mg/mL 10 mL ampules are on back order with an estimated release date of late-April, 2012. Infumorph 10 mg/mL and 25 mg/mL 20 mL ampules are on back order with an estimated release date of late-April to early-May, 2012.
- Hospira has morphine 2 mg/mL, 8 mg/mL, and10 mg/mL 1 mL Carpuject syringes, 5 mg/mL 30 mL vials, and 1 mg/mL 30 mL PCA vials on intermittent back order and the company is releasing product as it becomes available. Morphine 4 mg/mL Carpuject syringes and 50 mg/mL 20 mL vials are on back order and the company estimates a release date late-April, 2012. Morphine 0.5 mg/mL 10 mL vials may be available in limited supply. Morphine 25 mg/mL 1 mL preservative-free vials are on back order with an estimated release date of June, 2012. Morphine 15 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of mid-June, 2012.

Ondansetron Injection

[12 April 2012]

Products Affected - Description

Ondansetron 2 mg/mL vials

Ondansetron injection, 2 mg/mL, APP
2 mL vials, package of 25 (NDC 63323-0373-02)
20 mL multiple dose vials (NDC 63323-0374-20)

Ondansetron injection, 2 mg/mL, Apotex
2 mL vials, package of 5 (NDC 60505-0744-01) - *discontinued*
20 mL multiple dose vial (NDC 60505-0744-06) - *discontinued*

Ondansetron injection, 2 mg/mL, Baxter
1 mL vials (NDC 10019-0905-17) - *discontinued*

Ondansetron injection, 2 mg/mL, Bedford
20 mL vial (NDC 55390-0121-01)
2 mL vials, packages of 10 (NDC 55390-0121-10) - *discontinued*
2 mL Novaplus vials, packages of 10 (NDC 55390-0307-10) - *discontinued*
20 mL Novaplus vials, packages of 1 (NDC 55390-0307-01) - *discontinued*

Ondansetron injection, 2 mg/mL, Caraco
2 mL ampules (NDC 62756-0181-01) - *discontinued*
20 mL vials (NDC 62756-0182-01) - *discontinued*

Ondansetron injection, 2 mg/mL, Cura
2 mL vials, packages of 5 (NDC 46860-0087-06) - *discontinued*

Ondansetron injection, 2 mg/mL, Hospira
2 mL iSecure syringe (NDC 00409-1120-62) - *NDC discontinued*
2 mL iSecure syringe (NDC 00406-1120-12)
2 mL vials, packages of 25 (NDC 00409-4755-03)
20 mL vials (NDC 00409-4759-01)

Ondansetron injection, 2 mg/mL, West-Ward
20 mL vials (NDC 00143-9890-01)
20 mL Novaplus vials (NDC 00641-6079-01)

Ondansetron injection, 2 mg/mL, Teva
2 mL vials, packages of 5 (NDC 00703-7221-02) - *discontinued*
2 mL vials, packages of 25 (NDC 00703-7221-04)
20 mL vials (NDC 00703-7226-01)
20 mL vials, packages of 10 (NDC 00703-7226-03)

Ondansetron injection, 2 mg\mL, Wockhardt
2 mL vials, packages of 5 (NDC 64679-0726-01)
20 mL vials (NDC 64679-0727-01)

Zofran injection, 2 mg/mL, GlaxoSmithKline
2 mL vials, packages of 5 (NDC 00173-00442-02) - *discontinued*

Ondansetron 32 mg/50 mL premixed bags
Ondansetron injection, premixed bags, Baxter
32 mg/50 mL (NDC 00338-1762-41)

Ondansetron injection, premixed bags, Claris
32 mg/50 mL (NDC 36000-0014-06)

Ondansetron injection, premixed bags, Pfizer
32 mg/50 mL (NDC 00069-0700-12) - *discontinued*

Ondansetron injection, premixed bags, Sagent
32 mg/50 mL (NDC 25021-0776-50) - *discontinued*

Ondansetron injection, premixed bags, Teva
32 mg/50 mL (NDC 00703-7239-39)

Ondansetron injection, premixed bags, Hospira
32 mg/50 mL (NDC 00409-4760-24)

Ondansetron injection, premixed bags, West-Ward
32 mg/50 mL (NDC 00143-9771-06) - *discontinued*

Reason for the Shortage

Ondansetron 2 mg/mL vials

- Apotex, Sagent and Cura have discontinued their ondansetron injection.
- APP has ondansetron on shortage due to increased demand for the product.
- Teva discontinued ondansetron 2 mL vials in 5 count packages.
- Caraco temporarily discontinued ondansetron injection.
- Baxter has discontinued their ondansetron injection 1 mL vial. Baxter states the shortage of their 2 mL and 20 mL vials was due to increased demand for the product.
- West-Ward acquired Baxter's ondansetron vials for injection. West-Ward discontinued the ondansetron 20 mL vials in October, 2011.
- Bedford discontinued ondansetron 2 mg/mL 2 mL vials in May, 2011 to concentrate on the manufacturing of other products.
- Ben Venue voluntarily suspended all manufacturing and distribution in mid-November, 2011 on a temporary basis. Product will become available in stages as production resumes.
- Bedford Laboratories has temporarily suspended the distribution of Ben Venue Laboratories manufactured products. Availability of products is updated on the Bedford Laboratories website.
- GlaxoSmithKline have discontinued Zofran 2 mL vials.
- Hospira has ondansetron on shortage due to quality improvement issues.
- West-Ward has ondansetron on back order due to increased demand.

Ondansetron 32 mg/50 mL premixed bags

- Hospira has ondansetron premixed bags on shortage due to changes in the manufacturing process.
- Claris recalled all lots of their ondansetron premixed bags in mid-2010.
- Pfizer discontinued their ondansetron premixed bags in January, 2012.
- Sagent has discontinued their ondansetron premixed bags.
- Teva has ondansetron premixed bags on shortage due to manufacturing delays.
- West-Ward has discontinued their ondansetron premixed bags.

Available Products

Ondansetron 2 mg/mL vials
Ondansetron injection, 2 mg/mL, Pfizer
2 mL vials, package of 25 (NDC 00069-1340-16)
20 mL vials (NDC 00069-1340-02)

Zofran injection, 2 mg/mL, GlaxoSmithKline
20 mL vial (NDC 00173-0442-00)

Ondansetron injection, 2 mg/mL, West-Ward
2 mL vials, packages of 5 (NDC 00143-9891-05)
2 mL vials, packages of 25 (NDC 00143-9891-25)
2 mL Novaplus vials, packages of 25 (NDC 00641-6078-25)
2 mL Novaplus vials, packages of 25 (NDC 00641-6080-25)

Ondansetron 32 mg/50 mL premixed bags
No products are fully available.

Estimated Resupply Dates

Ondansetron 2 mg/mL vials

- APP recently released ondansetron 2 mL vials. Please check with wholesalers for inventory. APP has ondansetron 2 mL vials on back order with an estimated release date mid-April 2012. The 20 mL multiple dose vials are on back order and the company cannot estimate a release date.
- Bedford has ondansetron 2 mg/mL 20 mL vials on back order and the company cannot estimate a release date.
- Hospira has all ondansetron presentations on intermittent back order and the company is releasing product as it becomes available.
- Teva has ondansetron 2 mL vials on back order and the company estimates a release date in mid-April, 2012 The 20 mL vials are on back order and the company cannot estimate a release date. Product may be available for drop shipment.
- West-Ward has ondansetron 2 mg/mL 20 mL vials and 20 mL Novaplus vials on back order and the company cannot estimate a release date.
- Wockhardt has ondansetron 20 mL vials on back order with an estimated release date of late-April 2012. The 2 mL vials are also on back order, with no release date.

Ondansetron 32 mg/50 mL premixed bags

- Baxter has ondansetron 32 mg/50 mL premixed bags on back order with an estimated release date of June 2012.
- Claris has ondansetron 32 mg/50 mL premixed bags on back order and the company cannot estimate a release date.
- Hospira has ondansetron 32 mg/50 mL premixed bags on back order and the company estimates a release date in 2012.
- Teva has ondansetron 32 mg/50 mL premixed bags on back order and the company cannot estimate a release date.