



One Luitpold Drive, P.O. Box 9001, Shirley, New York 11967
 (631) 924-4000 • (800) 645-1706 • Fax (631) 924-1731

March 16, 2011

VIA EMAIL AND/OR FACSIMILE

URGENT: VOLUNTARY DRUG RECALL

**RE: DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP, 4 mg/mL
 NDC # 0517-4901-25, NDC # 0517-4905-25, NDC # 0517-4930-25**

Attention: Wholesaler/Distributor

Dear Sir or Madam:

This is to notify you that all unexpired lots (listed below) of Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL, 1 mL Single Dose Vial, NDC # 0517-4901-25; 5 mL Multiple Dose Vial, NDC # 0517-4905-25; and 30 mL Multiple Dose Vial, NDC # 0517-4930-25, distributed by American Regent, Inc., are the subject of a voluntary Recall by Luitpold Pharmaceuticals, Inc., as the manufacturer. Recall of this product was initiated because some vials of these lots either contain particulates or have the potential to form particulates prior to their respective expiration dates. Potential adverse events after intravenous administration of solutions containing particulates may include disruption of blood flow within small blood vessels in the lung, localized inflammation (swelling and redness due to accumulation of inflammatory cells), and granuloma formation. Intramuscular administration could result in foreign body inflammatory response, with local pain, swelling and possible long term granuloma formation. American Regent is undertaking this recall in consideration of the potential for safety issues, if these lots of product are administered to patients.

Dexamethasone Sodium Phosphate Injection, USP, is a synthetic adrenocortical steroid used to treat a variety of inflammatory and allergic conditions. See attached list.

The following Lots are under Voluntary Recall by all accounts to the USER or CONSUMER LEVEL. Further use or distribution of these lots of product should cease.

**Dexamethasone Sodium Phosphate Injection, USP
 1 mL SDV (NDC # 0517-4901-25)**

Lot Number	Expiration Date	First Distribution Date
9153	3/11	04/07/09
9170	3/11	04/15/09
9182	3/11	04/28/09
9218	3/11	05/06/09
9254	4/11	05/18/09
9295	4/11	05/27/09

Lot Number	Expiration Date	First Distribution Date
0215	3/11	04/22/10
0229	4/11	04/26/10
0245	4/11	05/05/10
0271	4/11	05/19/10
0277	4/11	06/01/10
0282	4/11	06/16/10

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Lot Number	Expiration Date	First Distribution Date
9329	5/11	06/08/09
9352	5/11	06/18/09
9368	5/11	06/30/09
9385	6/11	07/14/09
9422	6/11	07/24/09
9425	6/11	08/04/09
9441	6/11	08/14/09
9512	7/11	08/25/09
9549	8/11	09/08/09
9565	8/11	09/21/09
9605	9/11	09/30/09
9615	9/11	10/14/09
9615A	9/11	10/20/09
9656	9/11	10/26/09
9668	9/11	11/06/09
9690	10/11	11/08/09
9710	10/11	12/01/09
9722	10/11	12/14/09
9743	10/11	12/23/09
0135	3/11	04/01/10
0138	3/11	04/12/10
0164	3/11	04/13/10

Lot Number	Expiration Date	First Distribution Date
0296	4/11	06/30/10
0302	5/11	07/15/10
0305	5/11	07/28/10
0324	5/11	08/12/10
0331	5/11	08/24/10
0342	5/11	09/07/10
0409	6/11	09/21/10
0444	6/11	10/04/10
0593	9/11	10/13/10
0599	9/11	10/26/10
0639	9/11	11/08/10
0678	10/11	11/15/10
0710	10/11	11/23/10
0736	10/11	12/08/10
0773	11/11	12/21/10
0792	11/11	12/21/10
0803	11/11	12/28/10
0819	11/11	01/03/11
0836	12/11	01/25/11
0846	12/11	02/10/11
0853	12/11	02/23/11
0879	12/11	03/11/11

**Dexamethasone Sodium Phosphate Injection, USP
 5 mL MDV(NDC # 0517-4905-25)**

Lot Number	Expiration Date	First Distribution Date
9210	3/11	04/16/09
9250	4/11	05/18/09
9335	5/11	06/11/09
9393	5/11	07/06/09
9417	6/11	08/03/09
9516	8/11	09/02/09
9571	8/11	09/29/09
9620	9/11	10/21/09
9667	9/11	11/18/09

Lot Number	Expiration Date	First Distribution Date
0317	5/11	06/16/10
0392	6/11	07/14/10
0404	6/11	08/10/10
0407	6/11	09/01/10
0556	8/11	09/30/10
0624	9/11	10/26/10
0704	10/11	11/22/10
0765	11/11	12/20/10
0805	11/11	12/23/10

Lot Number	Expiration Date	First Distribution Date
0157	3/11	04/01/10
0217	3/11	04/27/10
0269	4/11	05/20/10

Lot Number	Expiration Date	First Distribution Date
0878	12/11	01/18/11
1055	1/12	02/22/11

**Dexamethasone Sodium Phosphate Injection, USP
 30 mL MDV (NDC # 0517-4930-25)**

Lot Number	Expiration Date	First Distribution Date
0213	3/11	05/04/10
0306	5/11	06/23/10
0387	6/11	08/02/10
0565	8/11	09/22/10

Lot Number	Expiration Date	First Distribution Date
0679	10/11	11/03/10
0771	11/11	12/22/10
0840	12/11	01/14/11

You are hereby instructed to isolate your inventory of the above mentioned lots of Dexamethasone Sodium Phosphate Injection, USP.

You are required to acknowledge receipt of this recall notification. Please notify us of quantities on hand, if any, by completing the attached form. As a direct account, please return product in inventory. If you have no product on hand, check the box, "We DO NOT Have Any Inventory of the Affected Lots of Product to Return." Please return the form electronically to recall@americanregent.com or via facsimile at 866-597-1991.

The Recall of these lots requires the return of product to American Regent, Inc. by all accounts to the **USER or CONSUMER LEVEL**. We request the following:

1. Contact the end user that purchased the lots listed of Dexamethasone Sodium Phosphate Injection, USP 1 mL SDV, NDC # 0517-4901-25 beginning distribution on April 7, 2009; 5 mL MDV, NDC # 0517-4905-25 beginning distribution on April 16, 2009; and 30 mL MDV, NDC # 0517-4930-25 beginning distribution on May 4, 2010; and alert them that American Regent has initiated a Recall and to immediately cease use of these lots of the product.
2. Instruct all end user customers to contact American Regent to arrange for product return by using our recall website at www.americanregent.com/recall/adx or by calling our Customer Service Department at 1-877-788-3232.
3. Provide American Regent with a list of end users.

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Be advised American Regent, Inc. will coordinate all customer returns. American Regent, Inc. will be responsible for all shipping costs incurred by you or your customers.

American Regent's Customer Service Department will reply via email or verbally with a Return Authorization number for your shipment of returned product.

We will arrange for the product to be returned to our Shirley, New York facility. Please prepare the shipment as follows:

American Regent, Inc.
26 Precision Drive
Shirley, NY 11967

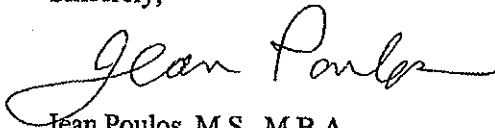
Attention: Shipping Department
RA # (to be issued)

A credit will be issued to your account. If you have any questions or problems regarding this matter, please contact the Sr. Director of Customer Service at (631) 924-4000, ext. 142.

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Your cooperation is appreciated.

Sincerely,



Jean Poulos, M.S., M.B.A.
Vice President, Quality & Regulatory Operations

**ATTACHMENT TO
DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP RECALL**

Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL is indicated for:

By intravenous or intramuscular injection when oral therapy is not feasible:

1. *Endocrine disorders*

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance)

Acute adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; mineralocorticoid supplementation may be necessary, particularly when synthetic analogs are used)

Preoperatively, and in the event of serious trauma or illness, in patients with known adrenal insufficiency or when adrenocortical reserve is doubtful

Shock unresponsive to conventional therapy if adrenocortical insufficiency exists or is suspected

Congenital adrenal hyperplasia

Nonsuppurative thyroiditis

Hypercalcemia associated with cancer

2. *Rheumatic disorders*

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

Post-traumatic osteoarthritis

Synovitis of osteoarthritis

Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)

Acute and subacute bursitis

Epicondylitis

Acute nonspecific tenosynovitis

Acute gouty arthritis

Psoriatic arthritis

Ankylosing spondylitis

3. *Collagen diseases*

During an exacerbation or as maintenance therapy in selected cases of:

Systemic lupus erythematosus

Acute rheumatic carditis

4. *Dermatologic diseases*

Pemphigus

Severe erythema multiforme (Stevens-Johnson syndrome)

Exfoliative dermatitis

Bullous dermatitis herpetiformis

Severe seborrheic dermatitis

Severe psoriasis

Mycosis fungoides

5. *Allergic states*
Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in:
Bronchial asthma
Contact dermatitis
Atopic dermatitis
Serum sickness
Seasonal or perennial allergic rhinitis
Drug hypersensitivity reactions
Urticarial transfusion reactions
Acute noninfectious laryngeal edema (epinephrine is the drug of first choice)
6. *Ophthalmic diseases*
Severe acute and chronic allergic and inflammatory processes involving the eye, such as:
Herpes zoster ophthalmicus
Iritis, iridocyclitis
Chorioretinitis
Diffuse posterior uveitis and choroiditis
Optic neuritis
Sympathetic ophthalmia
Anterior segment inflammation
Allergic conjunctivitis
Keratitis
Allergic corneal marginal ulcers
7. *Gastrointestinal diseases*
To tide the patient over a critical period of the disease in:
Ulcerative colitis (Systemic therapy)
Regional enteritis (Systemic therapy)
8. *Respiratory diseases*
Symptomatic sarcoidosis
Berylliosis
Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy
Loeffler's syndrome not manageable by other means
Aspiration pneumonitis
9. *Hematologic disorders*
Acquired (autoimmune) hemolytic anemia
Idiopathic thrombocytopenic purpura in adults (I.V. only; I.M. administration is contraindicated)
Secondary thrombocytopenia in adults
Erythroblastopenia (RBC anemia)
Congenital (erythroid) hypoplastic anemia
10. *Neoplastic diseases*
For palliative management of:
Leukemias and lymphomas in adults
Acute leukemia of childhood
11. *Edematous states*
To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type, or that due to lupus erythematosus

12. *Miscellaneous*
 Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy
 Trichinosis with neurologic or myocardial involvement
13. *Diagnostic testing of adrenocortical hyperfunction*
14. *Cerebral Edema* associated with primary or metastatic brain tumor, craniotomy, or head injury. Use in cerebral edema is not a substitute for careful neurosurgical evaluation and definitive management such as neurosurgery or other specific therapy.
- B. **By intra-articular or soft tissue injection:**
 As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
 Synovitis of osteoarthritis
 Rheumatoid arthritis
 Acute and subacute bursitis
 Acute gouty arthritis
 Epicondylitis
 Acute nonspecific tenosynovitis
 Post-traumatic osteoarthritis.
- C. **By intralesional injection:**
 Keloids
 Localized hypertrophic, infiltrated, inflammatory lesions of: lichen planus, psoriatic plaques, granuloma annulare and lichen simplex chronicus (neurodermatitis)
 Discoid lupus erythematosus
 Necrobiosis lipoidica diabetorum
 Alopecia areata
 May also be useful in cystic tumors of an aponeurosis or tendon (ganglia).