Delivering Efficiency to Healthcare

FAX COVER

From: *National Distribution & Contracting, Inc.* *Djana Milliken – Compliance* ***URGENT*** ****This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.**** **To:** *Purchasing or Regulations Department*	**Date:** *09/27/2017*
Pages: *7* *(Including cover page)*	
Regarding: *Pfizer Inc.* *Important Drug Warning* *Solu-Medrol 40 mg powder -Item # PFZ 0871*	

Comments:

Dear Distributor,

Attached is a letter we received from Pfizer Inc. regarding the recall on Solu-Medrol 40 mg powder. Our records indicate that you purchased this product from us. Please read attached letter. ***If you have any questions please contact Pfizer Customer Service at 844-646-4398. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.*** *Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you.*

Thanks,

Djana Milliken

Djana Milliken

407 New Sanford Road, La Vergne, TN 37086
compliance@ndc-inc.com / Phone: 615-324-6375 / Fax: 615-229-6801

Pfizer Injectables

Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045

September 2017

IMPORTANT DRUG WARNING

Subject: Contraindication for use of Solu-Medrol® (methylprednisolone sodium succinate for injection, USP) 40 mg powder and solvent for solution for injection in patients with a known or suspected hypersensitivity to cow's milk or its components, or other dairy products

Dear Healthcare Provider,

Pfizer would like to inform you of the following:

- Solu-Medrol® (methylprednisolone sodium succinate for injection, USP) 40 mg powder and solvent for solution for injection (NDC numbers 00009-0039-28 and 00009-0039-32) presentation includes lactose monohydrate produced from cow's milk. In a very small number of cases, serious allergic reactions, including bronchospasm and anaphylaxis have been reported in patients allergic to cow's milk proteins who were treated intravenously or intramuscularly with 40 mg methylprednisolone products containing lactose. This product is therefore contraindicated in patients with a known or suspected hypersensitivity to cow's milk or its components, or other dairy products, because they may contain trace amounts of milk ingredients.

- If a patient has signs or symptoms of hypersensitivity following administration of Solu-Medrol® (methylprednisolone sodium succinate for injection, USP), administration should be stopped, and the patient should be treated accordingly.

- In the treatment of acute allergic conditions, the use of corticosteroids which do not contain lactose from animal sources should be considered where appropriate, as use of Solu-Medrol® (methylprednisolone sodium succinate for injection, USP) in individuals with hypersensitivity to milk proteins has the potential to exacerbate the condition.

Pfizer Solu-Medrol® (methylprednisolone sodium succinate for injection, USP) 125 mg, 250 mg, 500 mg, 1000 mg and 2000 mg powder and solvent for solution for injection do not contain lactose.

Recommendations to Health Care Professionals and Wholesalers

It is not necessary to return the product, however, it is important that this information be provided to all appropriate staff. If you have further distributed this product to any other accounts, please communicate this important information to those accounts. Should you have any questions about this notification or require additional copies of this letter, please contact Stericycle at 1-888-206-4609 (Monday through Friday, 8:00am to 5:00pm ET) or email at Pfizer3211@stericycle.com and reference the event code number 3211.

Please contact Pfizer Customer Service at 1-844-646-4398 (Monday through Friday, 8:00am to 7:00pm ET) or your Pfizer representative for any questions you may have regarding this letter.

If you have any medical questions regarding this product, please contact Pfizer Medical Information at 1-800-438-1985 (Monday through Friday, 8:00am – 7:00pm ET).

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking Solu-Medrol to Pfizer at 1-800-438-1985. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You also may contact our medical information department at 1-800-438-1985 if you have any questions about the information contained in this letter or the safe and effective use of Solu-Medrol.

Important Safety Information

Solu-Medrol Sterile Powder is contraindicated in systemic fungal infections and patients with known hypersensitivity to the product and its constituents.

The Solu-Medrol 40 mg presentation includes lactose monohydrate produced from cow's milk. This presentation is therefore contraindicated in patients with a known or suspected hypersensitivity to cow's milk or its components or other dairy products because it may contain trace amounts of milk ingredients.

Solu-Medrol is contraindicated for intrathecal administration. Reports of severe medical events have been associated with this route of administration.

Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura.

Formulations preserved with benzyl alcohol are contraindicated for use in premature infants. These formulations are potentially toxic when administered locally to neural tissue.

Serious neurological events, some resulting in death, have been reported with epidural injection of corticosteroids.

Injection of Solu-Medrol may result in dermal and/or subdermal changes forming depressions in the skin at the injection site.

Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroid therapy.

In patients receiving the 40 mg presentation of Solu-Medrol during the treatment for acute allergic conditions and where these symptoms worsen or any new allergic symptoms occur, consideration should be given to the potential for hypersensitivity reactions to cow's milk ingredients. If appropriate, administration of SOLU-MEDROL should be stopped, and the patient's condition should be treated accordingly. Alternative treatments, including the use of corticosteroid formulations that do not contain ingredients produced from cow's milk, should be considered for acute allergy management, where appropriate.

Increased dosage of rapidly acting corticosteroids is indicated in patients on corticosteroid therapy who are subjected to any unusual stress before, during, or after the stressful situation.

High doses of systemic corticosteroids including Solu-Medrol should not be used for the treatment of traumatic brain injury.

Corticosteroids can cause elevation of blood pressure, salt and water retention, and increase excretion of potassium.

Therapy with corticosteroids should be used with great caution in patients with a recent myocardial infarction.

Corticosteroids can produce hypothalamic-pituitary adrenal axis suppression with the potential for glucocorticosteroid insufficiency after treatment withdrawal. Corticosteroids can also cause Cushing's syndrome and hyperglycemia.

Rarely, high doses of cyclically pulsed intravenous methylprednisolone can induce a toxic form of acute hepatitis.

Patients on corticosteroids are more susceptible to infections than healthy patients. Infections may be mild, but can be severe and at times fatal. Corticosteroids may mask some signs of current infection. Do not use intraarticularly, intrabursally, or for intratendinous administration for local effect in the presence of acute local infection.

A study failed to establish the efficacy of methylprednisolone sodium succinate in the treatment of sepsis syndrome and septic shock and suggested that certain patients may have a higher risk of mortality.

Corticosteroids may exacerbate systemic fungal infections and should not be used in the presence of such infections unless needed to control drug reactions.

Latent disease may be activated or there may be an exacerbation of intercurrent infections caused by certain pathogens. Consult the full Prescribing Information for these pathogens and restrictions.

Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered however the response to such vaccines cannot be predicted.

Chicken pox and measles can have a more serious or fatal course in pediatric and adult patients on corticosteroids.

Use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves and may enhance the establishment of secondary ocular infections due to bacteria, fungi or viruses. Corticosteroids should not be used in active ocular herpes simplex.

The lowest possible dose of corticosteroid should be used to control the condition under treatment. When dosage reduction is possible, the reduction should be gradual.

Use with caution in patients with congestive heart failure, hypertension, renal insufficiency, active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses and nonspecific ulcerative colitis. Corticosteroids decrease bone formation and increase bone resorption. An acute myopathy has been observed with high doses of corticosteroids. Psychic derangements may appear when corticosteroids are used.

Aminoglutethimide may lead to a loss of corticosteroid-induced adrenal suppression. Amphotericin B injection ad potassium-depleting agents may produce hypokalemia, cardiac enlargement and congestive heart failure. Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance. Concomitant use of anticholinesterase agents and corticosteroids may produce severe weakness in patients with myasthenia gravis. Coadministration with warfarin usually results in inhibition of response to warfarin. Dosage adjustments of antidiabetic agents may be required. Serum isoniazid concentrations may be decreased. Cholestyramine may increase corticosteroid clearance. When used concurrently with cyclosporine, convulsions have been reported. Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia. Estrogens may decrease the hepatic metabolism of certain corticosteroids. Drugs which induce cytochrome P450 3A4 enzyme activity may enhance the metabolism of corticosteroids. Drugs which inhibit cytochrome P450 3A4 have the potential to increase the plasma concentrations of corticosteroids. Ketoconazole can significantly decrease the metabolism of certain corticosteroids. Concomitant use of aspirin or other nonsteroidal anti-inflammatory agents increases the risk of gastrointestinal side effects.

Corticosteroids may suppress reactions to skin tests. Patients on prolonged corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines.

Corticosteroids should only be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Benzyl alcohol can cross the placenta.

Adverse effects of corticosteroids in pediatric patients are similar to those in adults.

Dose selection for elderly patients should be cautious due to greater frequency of decreased hepatic, renal, or cardiac function, concomitant disease or other drug therapy.

The following adverse reactions have been reported with Solu-Medrol or other corticosteroids:

Allergic or hypersensitivity reactions, anaphylactoid reaction, anaphylaxis, and angioedema. Leukocytosis. Bradycardia, cardiac arrest, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, and vasculitis. Acne, allergic dermatitis, burning or tingling, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses, petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, rash, sterile abscess, striae, thin fragile skin, thinning scalp hair, and urticaria.

Decreased carbohydrate and glucose tolerance, development of cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents, manifestations of latent diabetes mellitus, menstrual abnormalities, secondary adrenocortical and pituitary unresponsiveness, and suppression of growth in pediatric patients. Fluid retention, hypokalemic alkalosis, potassium loss and sodium retention. Abdominal distension, bowel/bladder dysfunction, elevation in serum liver enzyme levels, hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer, perforation of small and large intestine, and ulcerative esophagitis. Negative nitrogen balance. Aseptic necrosis of femoral and humeral heads, Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, postinjection flare, steroid myopathy, tendon rupture, and vertebral compression fractures. Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychic disorders, and vertigo. Arachnoiditis, meningitis, paraparesis/paraplegia and sensory disturbances. Exophthalmos, glaucoma, increased ocular pressure, rare instances of blindness. Abnormal fat deposits, hiccups, increased or decreased motility and number of spermatozoa, injection site infections, malaise, moon face and weight gain.

Indications and Usage

When oral therapy is not feasible, and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, the intravenous or intramuscular use of Solu-Medrol Sterile Powder is indicated as follows:

Allergic states-severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment

Dermatologic diseases-bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome).

Endocrine disorders-primary or secondary adrenocortical insufficiency, congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis.

Gastrointestinal diseases-regional enteritis (systemic therapy) and ulcerative colitis.

Hematologic disorders-acquired (autoimmune) hemolytic anemia, congenital (erythroid) hypoplastic anemia (Diamond-Blackfan anemia), idiopathic thrombocytopenic purpura in adults (intravenous administration only; intramuscular administration is contraindicated), pure red cell aplasia, selected cases of secondary thrombocytopenia.

Miscellaneous-trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy.

Neoplastic diseases-palliative management of leukemias and lymphomas.

Nervous System-acute exacerbations of multiple sclerosis; cerebral edema associated with primary or metastatic brain tumor, or craniotomy.

Ophthalmic diseases-sympathetic ophthalmia, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids.

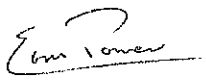
Renal diseases-to induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus.

Respiratory diseases- berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis.

Rheumatic disorders-adjunctive therapy for short-term administration in acute gouty arthritis; acute rheumatic carditis; ankylosing spondylitis; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, temporal arteritis, polymyositis, and systemic lupus erythematosus

Please see the attached package insert for full prescribing information, or to access electronically, go to http://www.pfizer.com/products/product-detail/solu_medrol

Yours Sincerely,



Eddie G M Power, PhD MBA,
US Medical Affairs Lead,
Chief Medical Office,
Pfizer Essential Health

9/27/2017

Pfizer Inc. - Item # 0871

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 Or email to: Compliance@ndc-inc.com

Acknowledgment of Receipt

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item #

☐ I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.

☐ We have inspected our inventory and have no product related to this recall

_____

Completed by: (Print Name /Signature/Date)

Returned Completed form to:

Fax #:
Email: