הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך: 2.8.17

שם תכשיר באנגלית ומספר הרישום:

Solu-Medrol 40mg/ml 025 48 22223

Solu-Medrol 125mg 126 13 20236

Solu-Medrol 500mg 114 09 22488

Solu-Medrol 1000mg 114 10 22489

שם בעל הרישום: פייזר פי אף אי פרמצבטיקה בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד!

ההחמרות המבוקשות

טקסט חדש	טקס נוכחי	פרק בעלון
Solu-Medrol 40mg/ml: in patients with a known hypersensitivity to cow's milk or its components, or other dairy products, because it contains trace amounts of milk ingredients.	------	**contraindications**
Immunosuppressant Effects/Increased Susceptibility to Infections Similarly, corticosteroids should be used with great care in patients with known or suspected parasitic infections such as Strongyloides (threadworm) infestation, which may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia. Live vaccines should not be given to individuals with impaired immune responsiveness. The antibody response to other vaccines may be diminished. … Immune System Effects Allergic reactions may occur. Rarely skin reactions and anaphylactic/anaphylactoid reactions have been reported following parenteral Solu-Medrol therapy. Physicians using the drug should be prepared to deal with such a possibility. Appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of drug allergy. Nervous System Effects Corticosteroids should be used with caution in patients with seizure disorders. Frequent patient monitoring is necessary in patients with epilepsy. Corticosteroids should be used with caution in patients with myasthenia gravis. (Also see myopathy statement in Musculoskeletal Effects section). Frequent patient monitoring is necessary in patients with myasthenia gravis. Severe medical events have been reported in	Immunosuppressant Effects/Increased Susceptibility to Infections Similarly, corticosteroids should be used with great care in patients with known or suspected parasitic infections such as Strongyloides (threadworm) infestation, which may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia Immune System Effects Allergic reactions may occur. Because rare instances of skin reactions and anaphylactic/anaphylactoid reactions have occurred in patients receiving corticosteroid therapy, appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of allergy to any drug. Nervous System Effects Corticosteroids should be used with caution in patients with seizure disorders. Frequent patient monitoring is necessary in patients with epilepsy. Corticosteroids should be used with caution in patients with myasthenia gravis. (Also see myopathy statement in Musculoskeletal Effects section below.) Frequent patient monitoring is necessary in patients with myasthenia gravis.	**Special Warnings and Special Precautions for Use**

association with the intrathecal/epidural routes of administration (see section 4.8). There have been reports of epidural lipomatosis in patients taking corticosteroids, typically with long-term use at high doses. Vascular Effects Steroids should be used with caution in patients with hypertension. Frequent patient monitoring is necessary. Thrombosis including venous thromboembolism has been reported to occur with corticosteroids. As a result, corticosteroids should be used with caution in patients who have or may be predisposed to thromboembolic disorders. Gastrointestinal Effects High doses of corticosteroids may produce acute pancreatitis. There is no universal agreement on whether corticosteroids per se are responsible for peptic ulcers encountered during therapy; however, glucocorticoid therapy may mask the symptoms of peptic ulcer so that perforation or haemorrhage may occur without significant pain. Glucocorticoid therapy may mask peritonitis or other signs or symptoms associated with gastrointestinal disorders such as perforation, obstruction or pancreatitis. Hepatobiliary Effects Drug induced liver injury including acute hepatitis or liver enzyme increase can result from cyclical pulsed IV methylprednisolone (usually at initial dose ≥ 1 g/day). Rare cases of hepatotoxicity have been reported. The time to onset can be several weeks or longer. In the majority of case reports resolution of the adverse events has been observed after treatment was discontinued. Therefore, appropriate monitoring is required.	Vascular Effects Steroids should be used with caution in patients with hypertension. Frequent patient monitoring is necessary. Gastrointestinal Effects There is no universal agreement on whether corticosteroids per se are responsible for peptic ulcers encountered during therapy; however, glucocorticoid therapy may mask the symptoms of peptic ulcer so that perforation or haemorrhage may occur without significant pain. Hepatobiliary Effects High doses of corticosteroids may produce acute pancreatitis.	
Table 2 *Important drug or substance interactions/effects with methylprednisolone* Contraceptives (oral) - ETHINYLESTRADIOL / NORETHISTERONE 2) Corticosteroids may induce the metabolism of HIV protease inhibitors resulting in reduced plasma concentrations. … Anticholinesterases Steroids may reduce the effects of anticholinesterases in myasthenia gravis. …	Table 2 *Important drug or substance interactions/effects with methylprednisolone* Contraceptives (oral) - ETHINYLESTRADIOL / NORETHISTERONE ------	**Interaction with other medicinal products and other forms of interaction**

Aromatase inhibitors - AMINOGLUTETHIMIDE Aminoglutethimide-induced adrenal suppression may exacerbate endocrine changes caused by prolonged glucocorticoid treatment.	Aromatase inhibitors - AMINOGLUTETHIMIDE Aminoglutethimide-induced adrenal suppression may impede endocrine changes caused by prolonged glucocorticoid treatment.	
The following adverse reactions have been reported with the following routes of administration: Intrathecal/Epidural: Arachnoiditis, functional gastrointestinal disorder/bladder dysfunction, headache, meningitis, paraparesis/paraplegia, seizure and sensory disturbances ***Metabolism and nutrition disorders*** ***Not Known*** - Metabolic acidosis, Epiduaral lipomatosis… ***Eye disorders*** ***Not Known*** – Chorioretinopathy… ***Respiratory, thoracic and mediastinal disorders*** ***Not Known*** - Pulmonary embolism… ***Hepatobiliary disorders*** ***Not Known*** - Hepatitis†; Increase of liver enzymes (e.g alanine aminotransferase increased (ALT, SGPT), aspartate aminotransferase increased (AST, SGOT)). † Hepatitis has been reported with IV administration (see section 4.4).	------ ***Metabolism and nutrition disorders*** ***Eye disorders*** ***Respiratory, thoracic and mediastinal disorders*** ------	**Undesirable effects**