

Cortef[®], Solu-Cortef[®] and Solu-Medrol[®] – New Warnings

- On September 8, 2016, the <u>FDA approved</u> new updates to the Warnings and Precautions sections of the <u>Solu-Cortef (hydrocortisone sodium succinate)</u> injection and <u>Cortef (hydrocortisone)</u> tablets drug labels regarding central serous chorioretinopathy, epidural lipomatosis and pheochromocytoma.
- Additionally, the <u>FDA approved</u> a new update to the Warnings and Precautions section of the <u>Solu-Medrol</u> (<u>methylprednisolone sodium succinate</u>) injection drug label regarding the risk of hepatotoxicity with high dose administration.
- Refer to the prescribing information for a complete list of labeled indications for Cortef, Solu-Cortef and Solu-Medrol.
- Other warnings and precautions for Solu-Cortef, Cortef and Solu-Medrol are found in the drug labels.
- A few other changes were made to the Solu-Cortef, Cortef and Solu-Medrol drug labels including the
 addition of leukocytosis to the Adverse Reactions section, removal of text regarding impaired
 mineralocorticoid secretion from the Precautions section and addition of non-clinical information regarding
 impairment of infertility.
 - For Solu-Cortef and Cortef, epidural lipomatosis and central serous chorioretinopathy were also added to the Adverse Reactions section.



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