June 18, 2025

Important Prescribing Information

Dear Customer,

Subject: Notice of inconsistency in the reconstituted storage instructions between the United States Prescribing Information (USPI) and the vial labels and carton for four (4) U.S. lots of Solu-Cortef® (hydrocortisone sodium succinate for injection, USP) 100 mg

Pfizer Inc. is issuing this letter to inform Health Care Providers (HCPs) of an inconsistency in the reconstituted storage instructions between the United States Prescribing Information (USPI) and the vial labels and cartons for four (4) U.S. lots of **Solu-Cortef® (hydrocortisone sodium succinate for injection, USP)** 100 mg. The Storage Conditions section of the USPI indicates that the product should be discarded after 12 hours if kept at room temperature or 24 hours if refrigerated, whereas the vial label and carton indicate to discard after 3 days.

Solu-Cortef® is an anti-inflammatory glucocorticoid that contains hydrocortisone sodium succinate as the active ingredient. Solu-Cortef® is available in several packages for intravenous or intramuscular administration.

- Solu-Cortef® is primarily used in hospitals for multiple indications and may be used in outpatient settings for patients in acute adrenal crisis, needing immediate injection or risk morbidity and/or mortality.
- Solu-Cortef®, 100 mg, Single Dose Fliptop Vial (0009-0825-01) may also be used in hospital settings and is commonly used for patients who require hydrocortisone administered via a continuous cortisol pump.

Prescriber Action

HCPs should adhere to the Storage Conditions section of the USPI, which contains the currently approved discard instructions that states that **reconstituted and/or further diluted product should be discarded after 12 hours if kept at room temperature or 24 hours if refrigerated**. The inconsistency in the reconstituted storage instructions does not necessitate returning the affected product.

Relevant excerpt of representative USPI for Solu-Cortef®:

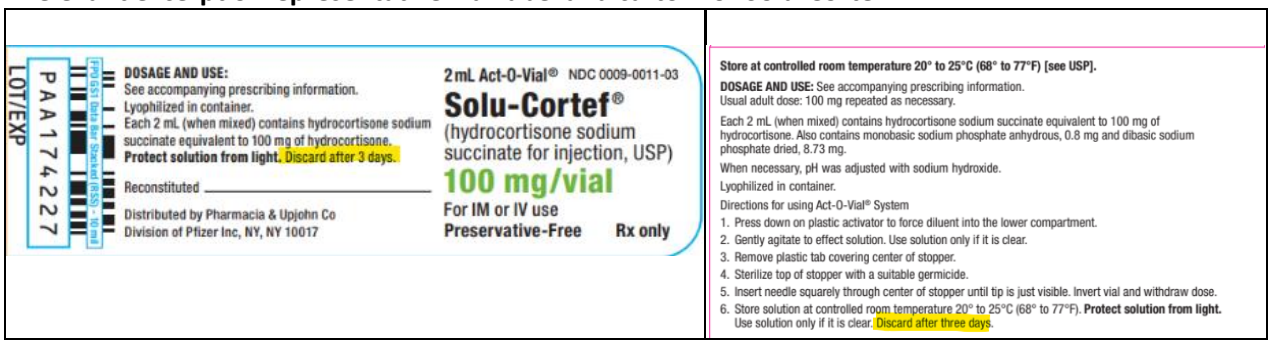
STORAGE CONDITIONS

Store unreconstituted product at controlled room temperature 20°C to 25°C (68°F to 77°F).

Store reconstituted and/or further diluted solution at controlled room temperature 20°C to 25°C (68°F to 77°F) and protect from light. Use the reconstituted and/or further diluted solution within 12 hours of preparation. Use reconstituted/diluted solution only if it is clear. If kept at controlled room temperature unused reconstituted and/or further diluted solution should be discarded after 12 hours post preparation. If kept under refrigerated conditions, unused reconstituted and/or further diluted solution should be used in no more than 24 hours and any unused portion should be discarded after that time.

For medical information about SOLU-CORTEF, please visit www.pfizermedinfo.com or call 1-800-438-1985. This product's label may have been updated. For current full prescribing information please visit www.pfizer.com

Relevant excerpt of representative vial label and carton for Solu-Cortef®:



For Wholesalers/Distributors, if you have further distributed the affected product lots to any other accounts, please communicate this information to those accounts immediately.

Please refer to Tables 1 and 2 for a complete listing of affected product lots and their expiration dates.

Table 1: Solu-Cortef® (hydrocortisone sodium succinate for injection, USP)

Vial NDC	Lot Number	Expiration Date	Strength/Packaging
0009-0825-01	LX6418	2027/11	100 mg/Vial
0009-0825-01	LX9087	2027/11	100 mg/Vial

Table 2: Solu-Cortef® Act-O-Vial (hydrocortisone sodium succinate for injection, USP)

Carton NDC	Vial NDC	Lot Number	Expiration Date	Strength/Packaging
0009-0011-04	0009-0011-03	MD0456	2027/10	100 mg/Vial
0009-0011-04	0009-0011-03	MF5652	2027/09	100 mg/Vial

Reporting Adverse Events and Product Complaints

Please contact Pfizer Customer Service at 844-646-4398 (Mon.-Fri. 8 am-6 pm ET), your Pfizer representative or the appropriate contacts listed below for any questions you may have regarding this letter.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET) www.pfizermedinfo.com	For medical questions regarding this product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day, 7 days per week)	Report adverse events or product complaints

Adverse events or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Complete and submit a report online: www.fda.gov/medwatch/report.htm.
- Regular mail or fax: download a reporting form from www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form. Complete the form and return it to the specified address on the form, or submit the form by fax to 800-FDA-0178 (800-332-0178).

Please see the Full U.S. Prescribing Information at labeling.pfizer.com/showlabeling.aspx?id=641.

We appreciate your immediate attention and cooperation and regret any inconvenience this issue may cause you.

Sincerely,

Najah Sampson

Najah Sampson
U.S. Hospital Lead
Pfizer Inc.