

DR. F. KÖHLER CHEMIE

Pharmaceuticals



Dr. Franz Köhler Chemie GmbH, Werner-von-Siemens-Str.14-28, 64625 Bensheim, Germany

Customer Information

CUSTODIOL® HTK 1000ml/2000ml/5000ml polymer bags

August 13, 2019

Dear Valued Customer,

Dr. Franz Köhler Chemie GmbH ("Koeehler Chemie") is writing to convey important information about CUSTODIOL® HTK Solution which is intended for the perfusion and flushing of donor kidney, liver, heart, and pancreas prior to removal from the donor and for preserving these organs during storage and transport. Koeehler Chemie is ceasing further US sales for all **CUSTODIOL® HTK in 1000/2000/5000ml polymer bags**.

Any product packaged in polymer bags that you already have received from our US distributor, Essential Pharmaceuticals, may be used as long as it has not reached the expiry date, please see the product information included in the CUSTODIOL® HTK shipment for further details if needed.

CUSTODIOL® HTK is cleared by the United States Food and Drug Administration (FDA) for use in glass bottles. Koeehler Chemie is working to submit required data to the FDA to support the polymer bag packaging.

Koeehler Chemie will offer CUSTODIOL® HTK in 1000ml glass bottles, and those bottles will be available through our US distribution partner, Essential Pharmaceuticals, starting the week of September 9, 2019 and until Koeehler Chemie resolves this issue.

We anticipate that CUSTODIOL® HTK 1000/2000/5000ml polymer bags will not be available for sale in the US through the end of 2019. Koeehler Chemie recommends that healthcare facilities inform their organ transplant staff about the change in availability of CUSTODIOL® HTK from polymer bags to glass bottles.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax, and to Koeehler Chemie at Pharmacovigilance department Email: Pharmacovigilance@koeehler-chemie.de or phone: +49 (0)6251 1083-100.

We apologize for any inconvenience. Customers with questions or requiring assistance should contact see below.

Sincerely

Frauke Weiß
CEO

Distributed by
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