

UPDATED URGENT LIDOCAINE HYDROCHLORIDE INJECTION, USP AND BUPIVACAINE HYDROCHLORIDE IN DEXTROSE INJECTION, USP RECALL

DATE OF MAILING

Dear Customer,

This is to inform you of a voluntary product recall involving LIDOCAINE HYDROCHLORIDE INJECTION, USP (ALL LOTS) and BUPIVACAINE HYDROCHLORIDE IN DEXTROSE INJECTION, USP (ALL LOTS). The purpose of this updated letter is to provide an updated combined response form.

Product Description	Strength	NDC Number	Dosage Unit	Configuration/Count
LIDOCAINE HCL INJECTION	10 mg/mL	71351-021-10	5-mL Vial	10 vials in 1 carton/box
LIDOCAINE HCL INJECTION	10 mg/mL	71351-021-25	5 mL Vial	25 vials in 1 carton/box
LIDOCAINE HCL INJECTION	20 mg/mL	71351-023-10	5 mL Vial	10 vials in 1 carton/box
LIDOCAINE HCL INJECTION	20 mg/mL	71351-023-25	5 mL Vial	25 vials in 1 carton/box
LIDOCAINE HCL INJECTION	10 mg/mL	71351-021-05	5 mL Vial	5 mL single-use vial
LIDOCAINE HCL INJECTION	20 mg/mL	71351-023-05	5 mL Vial	5 mL single-use vial
LIDOCAINE HCL INJECTION	10 mg/mL	73293-0001-2	5-mL Vial	10 vials in 1 carton/box
LIDOCAINE HCL INJECTION	10 mg/mL	73293-0001-1	5-mL Vial	Single-use vial
LIDOCAINE HCL INJECTION	20 mg/mL	73293-0003-2	5-mL Vial	10 vials in 1 carton/box
LIDOCAINE HCL INJECTION	20 mg/mL	73293-0003-1	5-mL Vial	5 mL single-use vial
LIDOCAINE HCL INJECTION	10 mg/mL	73293-0001-1	5-mL Vial	5 mL single-use vial
LIDOCAINE HCL INJECTION	10 mg/mL	73293-0001-2	5-mL Vial	10 vials in 1 carton/box
LIDOCAINE HCL INJECTION	10 mg/mL	84769-0001-2	5-mL Vial	10 vials in 1 carton/box
LIDOCAINE HCL INJECTION	10 mg/mL	84769-0001-1	5-mL Vial	5 mL single-use vial
LIDOCAINE HCL INJECTION	20 mg/mL	84769-0002-2	5-mL Vial	10 vials in 1 carton/box
LIDOCAINE HCL INJECTION	20 mg/mL	84769-0002-1	5-mL Vial	5 mL single-use vial
LIDOCAINE HCL INJECTION	10 mg/mL	63739-170-24	5-mL Vial	10 vials in 1 carton/box
LIDOCAINE HCL INJECTION	10 mg/mL	63739-170-27	5-mL Vial	25 vials in 1 carton/box
LIDOCAINE HCL INJECTION	10 mg/mL	63739-170-13	5-mL Vial	5 mL single-use vial
LIDOCAINE HCL INJECTION	20 mg/mL	68094-081-25	5-mL Vial	25 vials in 1 carton/box
LIDOCAINE HCL INJECTION	20 mg/mL	68094-081-01	5-mL Vial	5 mL single-use vial
BUPIVACAINE HCL INJECTION	7.5 mg/mL	73293-0002-2	2mL ampule	50 ampules in 1 package
BUPIVACAINE HCL INJECTION	7.5 mg/mL	73293-0002-1	2mL ampule	Single-use Ampule label
BUPIVACAINE HCL INJECTION	7.5 mg/mL	71351-022-10	2mL ampule	10 ampules in 1 package
BUPIVACAINE HCL INJECTION	7.5 mg/mL	71351-022-50	2mL ampule	50 ampules in 1 package
BUPIVACAINE HCL INJECTION	7.5 mg/mL	71351-022-02	2mL ampule	Single-use Ampule label
LIDOCAINE HCL INJECTION	10 mg/mL	58181-7010-1	5-mL Vial	10 vials in 1 case
LIDOCAINE HCL INJECTION	10 mg/mL	58181-7025-1	5-mL Vial	25 vials in 1 case
LIDOCAINE HCL INJECTION	20 mg/mL	58181-8010-2	5-mL Vial	10 vials in 1 case
LIDOCAINE HCL INJECTION	20 mg/mL	58181-8025-2	5-mL Vial	25 vials in 1 case
LIDOCAINE HCL INJECTION	10 mg/mL	65282-1605-1	2mL ampule	25 ampules in 1 case
SODIUM CHLORIDE INJECTION	9.0 mg/mL	65282-1510-1	2mL ampule	25 ampules in 1 case

5153_04_01AS_V1.1

Huons Co., Ltd.

Head Office : 8th Floor, HuonsGlobal Bldg., 17 Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, Republic of Korea

1st Factory : 100, Bio Valley-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea

084110.KQ www.huons.com

2nd Factory : 137, Bio Valley-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea

Huons Co. Ltd. is voluntarily recalling all lots of the above referenced product due to quality issues identified during a recent FDA manufacturing facility inspection. We began shipping the Lidocaine Hydrochloride Injection on or about **May 1, 2023** and the Bupivacaine Hydrochloride in Dextrose Injection on or about **April 1, 2023**. Use of or consumption of this product may include a potential health hazard.

During this period, Huons has only received a small number of reports of drug ineffectiveness.

FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM"

- Immediately examine your inventory and discontinue use, stop distribution, and quarantine product subject to recall
- Contact Sedgwick at 877-550-0701 or huons5153@sedgwick.com and request return paperwork
- Fill out the individual response form and return via one of the below methods (even if you don't have any product):
 - Fax: 877-223-7696
 - Email: huons5153@sedgwick.com
- Package and complete your product return with the individual shipping label received and include the packing slip
 - Please note: if additional labels are needed, you can call Sedgwick at 877-550-0701 or contact UPS to request additional labels

Your assistance is appreciated and necessary to prevent potential patient harm.

Please complete and return the enclosed Business Reply Card as soon as possible. If you have questions, call Sedgwick at 877-550-0701 (Monday–Friday, 8:00 a.m.–5:00 p.m. EST).

This recall is being made with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience this action may cause you.

Thank you for your consideration,

Song, Soo Yong
CEO

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