

**URGENT PRODUCT RECALL
SAFETY NOTICE****Xylocaine® (lidocaine HCl) 2% Jelly Single Use Plastic Syringe (10mL)****Product No. 063 DIN 00385484****ATTENTION: Healthcare Professionals**

Please be advised that AstraZeneca has identified an issue related to the break seal construction of this syringe product and how the seal is being opened. It has been determined that:

- On breaking the seal, it is possible for the seal to be broken at the wrong point.
- This creates the potential for a plastic fragment (approx. 2mm x 5mm) to break away and lodge in the applicator tip of the syringe.
- If this happens, the plastic fragment may block the syringe or enter the Jelly.
- If the plastic fragment enters the Jelly, there is a risk that the plastic fragment may be dispersed with the Jelly.

Therefore, in consultation with Health Canada, AstraZeneca is initiating a Type II product recall to all customers for Xylocaine® 2% Jelly Single Use Plastic Syringe (10mL) product currently on the market.

Please follow the instructions below:

1) If you **do not have** affected product:

- Please indicate this on the attached Healthcare Professional Response Form and immediately fax back to AstraZeneca at 1-800-268-0774.

2) If you **do have** affected product:

- **Please discontinue use of this product**
- Please complete the attached Healthcare Professionals response form and immediately fax back to AstraZeneca Canada Inc. at 1-800-268-0774.
- Upon receipt of your fax, AstraZeneca will provide you with a return authorization number.
- Please indicate the return authorization number on the product when you return it.
- Once the product has been received, your account will be credited.

Please inform any of your patients that have this product about this recall and that they should return the product to the pharmacy that they purchased it from. A public advisory will be issued and posted on Health Canada's website, http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/index_e.html.

In anticipation of inquiries about alternatives, please note that AstraZeneca has limited supply of Xylocaine® Jelly 2% in a 30 mL aluminum tube format (product # 061, DIN 00001694) which is approved for the same indications as Xylocaine® 2% Jelly Syringe. The tube format is sterile in the blister package and contains preservatives (methylparaben and propylparaben) for multiple use. However once the tube is opened, it is no longer sterile. No Xylocaine® product other than the plastic syringe is affected by the recall.

We appreciate your cooperation and regret any inconvenience this may cause. Should you require any further assistance, please call Customer Relations at 1-800-668-6000.

Sincerely,
AstraZeneca Canada Inc.



URGENT PRODUCT RECALL

Xylocaine® (lidocaine HCl) 2% Jelly Single Use Plastic Syringe (10mL)

Product No. 063 DIN 00385484

HEALTHCARE PROFESSIONALS RESPONSE FORM

| Lot Number | Qty to be returned (# of syringes) | Lot Number | Qty to be returned (# of syringes) | Lot Number | Qty to be returned (# of syringes) |
|------------|------------------------------------|------------|------------------------------------|------------|------------------------------------|
| FH896 | | GE944 | | HA1005 | |
| FI897 | | GE949 | | HA1006 | |
| FK904 | | GF955 | | HC1016 | |
| FK909 | | GH958 | | HC1021 | |
| GA918 | | GI963 | | HD2003 | |
| GA924 | | GI966 | | HE2008 | |
| GC932 | | GK971 | | HF2013 | |
| GC934 | | GL979 | | | |
| GD939 | | GM1004 | | | |

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| Name | |
| Title | |
| Company | |
| Address | |
| Postal Code | |
| Telephone Number | |
| Fax Number | |
| Account Number | |
| Return Authorization Number | |

FAX THE COMPLETED FORM TO 1-800-268-0774

THANK YOU