

URGENT TYPE III RECALL of NEORAL* (cyclosporine oral solution) 100 mg/mL lot H5131



January 8th, 2013

RETURN PROCEDURE & FORM FOR DISTRIBUTORS/WHOLESALERS/PHARMACISTS

VOLUNTARY RECALL of NEORAL* (cyclosporine oral solution) 100 mg/mL - DIN 02150697, 50 mL bottles - lot H5131

NOVARTIS Pharmaceuticals Canada Inc. (“Novartis”), in consultation with Health Canada, has decided to initiate a voluntary Type III recall at the wholesaler and pharmacist levels due to the potential defect in the neck of the glass bottle of NEORAL* (cyclosporine oral solution) 100 mg/mL, DIN 02150697, 50mL bottles, lot H5131 (expiry date: 31 January 2015).

Please return **immediately** all **NEORAL* (cyclosporine oral solution) 100 mg/mL**, with lot number **H5131only**, held in your facilities and complete the attached form. If you have further distributed product as a distributor/wholesaler, it is your responsibility to advise those customers that have purchased lot H5131, of the recall and request they return the product as per the return process detailed below.

| Reason for Voluntary Recall |
|---|
| Neoral* (cyclosporine oral solution) 100 mg/mL, for Lot H5131 only is at risk of leaking and/or having broken bottle necks. During the filling operation for this lot at the manufacturer, some bottles were damaged at the neck due to incorrect set up of the crimping machine. Consequently, there may be leakage. Furthermore, bottle necks may break upon opening. The incorrect set up of the crimping machine was detected and fixed during filling. Therefore, the defect is limited to lot H5131 only, and the defect is detectable. |

| Special Instructions |
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| Send the product, marked as “ NEORAL* Return – Not for use” (Distributors/Wholesalers to forward recall notice to their customers who purchased lot H5131) <ul style="list-style-type: none"> Send returns collect by contacting Purolator, account #2333183 at 1-888-744-7123 Send returns to the following address: CLS Med-Turn International Inc. 2121 McCowan Road, Unit #1 Toronto, Ontario M1S 3Y6 (Tel: 1-888-784-2323) If you have any questions, please contact Novartis’s Customer Relations at 1-800-465-2244 (customer.relations@novartis.com) or Medical Information at 1-800-363-8883(medinfo.canada@novartis.com) |

| Credit of return |
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| <ul style="list-style-type: none"> For Wholesalers and Distributors, all returned stock will receive 100% credit based upon Novartis’s current national list price plus a 5% credit for distribution fees. For hospitals, replacement product will be provided for the returned stock. |

| Distributor/Pharmacy | |
|-----------------------------|---|
| Distributors Name: | or Pharmacy Name: |
| Novartis Account Number: | Novartis Account Number: |
| Address: | Address: |
| Contact Name: | Pharmacy Contact Name: |
| Telephone #: | Telephone # : |
| Date of return: | Date: |
| | Name of your Distributor /Wholesaler: |
| | Account# with your Distributor /Wholesaler: |

| INVENTORY ON HAND – RETURNS | | |
|------------------------------------|----------------------|-----------|
| | Units ⁽¹⁾ | Lot H5131 |
| total | | |

- Unit: One unit equals a bottle of 50ml.
- Please include a copy of this form with the return.** Keep a copy for your files.
- Pharmacists: Please ensure to specify your Distributor name and account number.

* NEORAL is a registered trademark