janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

October 23, 2018

URGENT DRUG RECALL

Dear Wholesaler/Distributor or Pharmacist,

Janssen Pharmaceuticals, Inc. is initiating a voluntary recall of one (1) lot of ORTHO-NOVUM® 1/35 and two (2) lots of ORTHO-NOVUM® 7/7/7 tablets in Veridate dispenser pack.

Product Description	NDC Number	Lot no.	Expiration Date	Distribution Dates
ORTHO-NOVUM® 1/35	5045817606	18BM114	03/2020	05-10-2018 – 09-21-2018
ORTHO-NOVUM® 7/7/7	5045817806	18CM120	03/2020	04-10-2018 – 09-21-2018
ORTHO-NOVUM® 7/7/7	504581781203	18BM110	03/2020	08-30-2018 – 08-30-2018

This voluntary recall is being initiated because the Brief Summary included in the Veridate dispenser does not include instructions to use the Veridate dispenser. Only instructions for the previous dispenser (Dialpak) are included. Only the three lots listed above are impacted by this issue and no other lots are being recalled.

The potential risk of having received packaged norethindrone/ethinyl estradiol tablets with missing instructions for use of the Veridate dispense pack includes possible medication error or drug dose omission. Although the likelihood of such an occurrence appears low, it could potentially lead to contraceptive failure.

The recall will be undertaken at the Wholesaler/Distributor and Pharmacy level.

IMMEDIATE ACTION TO BE TAKEN:
See following page.

Wholesaler/Distributor:

1. Please examine your inventory to determine if you have any of the referenced lots. If so, discontinue distribution of the product from the referenced lots.
2. If you are a wholesaler/distributor and have further distributed any product from these lots to pharmacies, please forward this recall communication and enclosed Prescribing Information (not the Business Reply Card) to your customer and request them to contact Stericycle at 888-731-7972 for a return package.
3. Record the quantity of referenced product in inventory on the Business Reply and Packing Slip, which is included with this letter.
4. Mail the Business Reply Card to Stericycle even if you do not have the referenced product in inventory.
5. Return the referenced product and the Packing Slip using the prepaid UPS *Return Service* shipping labels to:

Stericycle, Inc.
Event Number: 8614
2670 Executive Dr., Suite A
Indianapolis, IN 46241

Pharmacies:

1. Please examine your inventory to determine if you have any of the referenced lots. If so, discontinue distribution of the product from the referenced lots.
2. Please do not return product to your wholesaler – contact Stericycle for a product return package and follow instructions in the return package to receive appropriate credit.
3. If you have any medical inquiries or other product-related questions regarding ORTHO-NOVUM® 1/35 or ORTHO-NOVUM® 7/7/7, please contact the Janssen Medical Information Center at 1-800-526-7736 (Monday – Friday, 9:00 am – 8:00 pm EST).

Please only return product from the referenced lot numbers. No credit will be issued for product returned from any other lots.

Credit will be based on the customer's ORTHO-NOVUM® 1/35 or ORTHO-NOVUM® 7/7/7, acquisition price in effect as of the date of this letter and issued in the form of a credit memo through the customer's authorized wholesaler or specialty distributor. This is applicable for the recalled lots only. Recalled product must be returned by March 2020 to be eligible for credit.

We appreciate your immediate attention and cooperation in this matter. **If you have any questions or need assistance with product return, contact Stericycle at 888-731-7972 (Monday – Friday, 8:00 am – 5:00 pm EST).**

The recall is being conducted with the knowledge of the U.S. Food and Drug Administration.