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Janssen Issues Voluntary Nationwide Recall for one lot of ORTHO-NOVUM® 1/35 and two lots of ORTHO-NOVUM® 7/7/7 Due to Incorrect Veridate® Dispenser Instructions

The ORTHO-NOVUM® product itself remains safe and effective for use with the appropriate dispenser instructions

TITUSVILLE, NJ, November 2, 2018 – Janssen Pharmaceuticals, Inc. has initiated a voluntary recall of one lot of ORTHO-NOVUM® 1/35 (norethindrone/ethinyl estradiol) Tablets and two lots of ORTHO-NOVUM® 7/7/7 (norethindrone/ethinyl estradiol) Tablets to the pharmacy level. The patient information provided inside affected packages of ORTHO-NOVUM® does not include the appropriate instructions for the Veridate® dispenser.

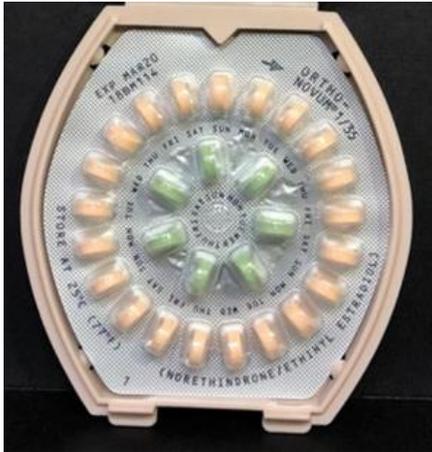
The potential risk of taking ORTHO-NOVUM® without the appropriate instructions for correct use of the Veridate® dispenser pack is that the consumer could take the pills in the incorrect order (still receiving an effective dose) or could take an inactive “reminder” pill instead of an “active” pill which could lead to breakthrough bleeding or an unintended pregnancy.

ORTHO-NOVUM® 1/35 and ORTHO-NOVUM® 7/7/7 tablets are indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception.

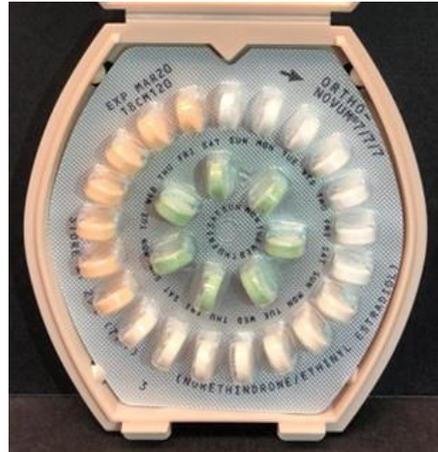
The ORTHO-NOVUM® product itself remains safe and effective for use with the appropriate dispenser instructions. Women should continue to take the 21 “active” pills (with hormones) (peach for ORTHO-NOVUM® 1/35; white, light-peach and

peach for ORTHO-NOVUM® 7/7/7) for three weeks, followed by the one week of green “reminder” pills (without hormones).

ORTHO-NOVUM® 1/35



ORTHO-NOVUM® 7/7/7



The three lots affected by this recall are:

Product Description	NDC Number (carton)	NDC Number (pouch)	Lot No.	Expiration Date
ORTHO-NOVUM® 1/35	50458-176-06	50458-176-28	18BM114	03/2020
ORTHO-NOVUM® 7/7/7	50458-178-06	50458-178-28	18CM120	03/2020
ORTHO-NOVUM® 7/7/7	50458-178-12	50458-178-12	18BM110	03/2020

This recall only affects the U.S., and no other ORTHO® contraceptive products beyond the three lots listed above are impacted by this recall action. ORTHO TRI-CYCLEN LO®, ORTHO TRI-CYCLEN®, ORTHO MICRONOR® and ORTHO CYCLEN® are not affected.

Products were distributed in the U.S. to wholesalers, distributors and pharmacies, and they have been notified by recall letter to return affected products.

Consumers with ORTHO-NOVUM® product from the affected lots can access the correct instructions for the Veridate® dispenser pack at

<https://www.janssen.com/us/our-products> and talk to their prescribing medical

professional if they have any concerns. Consumers should not stop taking the product and if they do miss a dose, they should follow the instructions included in the packet.

Consumers with questions regarding this recall can contact Janssen via phone on: 1-800-526-7736 (1-800-JANSSEN) Monday through Friday from 9:00 am to 8:00 pm ET. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

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.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178

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

About the Janssen Pharmaceutical Companies

Janssen Pharmaceuticals, Inc. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Learn more at www.janssen.com.

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