ORTHO-NOVUM® 1/35 and 7/7/7 (norethindrone/ethinyl estradiol)
VOLUNTARY RECALL FACT SHEET FOR PATIENTS

At Janssen, we believe our first responsibility is to the individuals who use our products and everything we do must be of high quality.

The patient information provided inside packages of one lot of ORTHO-NOVUM® 1/35 and two lots of ORTHO-NOVUM® 7/7/7 did not include the appropriate instructions for the Veridate® dispenser. On October 23, 2018 we initiated a voluntary recall at the pharmacy level of affected lots.

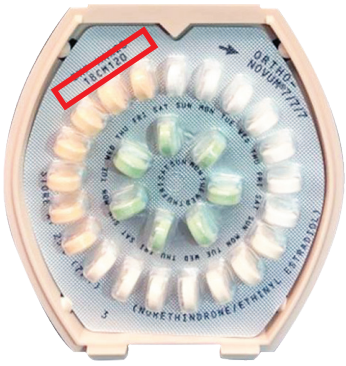
The ORTHO-NOVUM® product itself remains safe and effective for use with the appropriate dispenser instructions.

Women should continue to take the 21 "active" pills for three weeks, followed by the one week of "reminder" pills.

How do I know if my ORTHO-NOVUM® 1/35 or 7/7/7 is impacted by this voluntary recall?

You can confirm if your ORTHO-NOVUM® tablets are affected by looking for the lot number just below the expiration date in the upper left-hand corner of the blister pack.

We are voluntarily recalling ORTHO-NOVUM® lots 18BM114, 18BM110 and 18CM120 because the information provided inside the affected packages does not include the appropriate instructions for the Veridate® dispenser currently used.



If you have any concerns, we recommend you speak to your prescribing physician.

Is it safe to continue taking ORTHO-NOVUM® 1/35 and 7/7/7?

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

If for any reason you choose to stop taking ORTHO-NOVUM® you should first speak with your prescribing physician and if you miss a dose you should follow the instructions included in the packet.

How do I find the correct use instructions for ORTHO-NOVUM® 1/35 and 7/7/7?

You can find the correct instructions for the Veridate® dispenser pack for ORTHO-NOVUM® 1/35 or ORTHO-NOVUM® 7/7/7 here.

Per these 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).

If you have any questions or concerns about how to take your medication, please speak to your prescribing physician.

Can I get pregnant if my ORTHO-NOVUM® 1/35 or 7/7/7 is part of the voluntary recall?

The potential risk of taking ORTHO-NOVUM® without the appropriate instructions for correct use of the Veridate® dispenser pack is that you could take the pills in the incorrect order or you could take an inactive "reminder" pill instead of an "active" pill which could lead to breakthrough bleeding or an unintended pregnancy.

Can I take another oral contraceptive?

There are readily available alternative oral contraceptive products on the market. However, to avoid breakthrough bleeding or an unintended pregnancy, you should not stop taking ORTHO-NOVUM® without first speaking to your prescribing physician or health care provider.

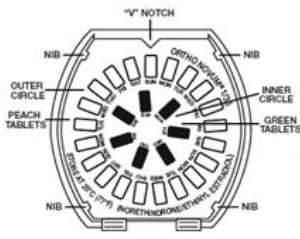
Are any other products affected by this voluntary recall?

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

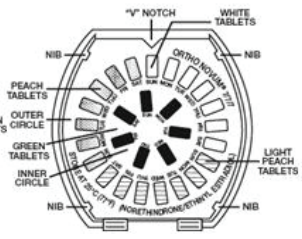
Who can I call to get more information?

You 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. You should contact your prescribing physician or healthcare provider if you have experienced any problems that may be related to taking or using this product.

ORTHO NOVUM 1/35



ORTHO NOVUM 7/7/7



Have questions on how to take your ORTHO-NOVUM® tablets? Visit https://www.janssen.com/us/veridate-dispenser-instructions for more information

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