

## Important Safety Information on ALESSE® 21 and ALESSE® 28: Packages Containing Broken or Split Tablets



2017/12/09

### Audience

Health care professionals including physicians, pharmacists and nurses.

### Key messages

- **Blister packages for ALESSE 21 and ALESSE 28 were found to contain one broken pink tablet in a sealed blister.**
- **Broken or split birth control tablets may deliver a smaller dose of the active drug ingredients, which could reduce its effectiveness in preventing pregnancy.**
- **Health care professionals are advised to remind their patients to:**
  - **check tablets before taking them and not consume tablets that are broken or split;**
  - **return blister packages containing broken or split tablets to the pharmacy to get a replacement package; and**
  - **seek counsel on the proper use of oral contraceptives, and on what to do if they miss a dose.**

### What is the issue?

Health Canada and Pfizer Canada Inc. have received reports for packages of ALESSE 21 and ALESSE 28 where the blister packages contained a single active (pink) tablet that was broken (see pictures below). This could reduce the dose of hormones and potentially result in an unintended pregnancy due to insufficient action of the contraceptive hormones levonorgestrel and ethinyl estradiol.

Top view of ALESSE 28 blister package with broken tablet circled in red:



Side view of ALESSE 28 blister package with broken tablet circled in red:



### Products affected

ALESSE 21 (Levonorgestrel and Ethinyl Estradiol), DIN 02236974

ALESSE 28 (Levonorgestrel and Ethinyl Estradiol), DIN 02236975

## **Background information**

ALESSE is a prescription medicine used for:

- Conception control.
- Treatment of moderate acne vulgaris in women  $\geq 14$  years of age who have no known contraindications to oral contraceptive therapy, desire contraception, and have achieved menarche.

The ALESSE 21 consists of 21 pink tablets containing active ingredients. ALESSE 28 consists of 21 pink tablets containing active ingredients, followed by 7 days of white tablets containing placebo.

During manufacturing, it is possible for tablets to break or split. However, as the manufacturing process is well controlled, these problems rarely occur and Pfizer considers these cases to be isolated incidents. The overall quality of the intact tablets is not affected.

There is a chance the consumer may decide not to take the broken tablet. This could reduce the dose of hormones and potentially result in an unintended pregnancy due to insufficient action of the contraceptive hormones levonorgestrel and ethinyl estradiol.<sup>1</sup>

## **Information for consumers**

ALESSE is a birth control tablet (oral contraceptive) that contains two female sex hormones (levonorgestrel and ethinyl estradiol). Packages of ALESSE 21 should have two rows of pink (active) tablets. Packages of ALESSE 28 should have two rows of pink (active) tablets and one row of white inactive (no hormones) tablets.

Patients are advised to thoroughly check their ALESSE birth control tablets before and after taking them out of the blister package to ensure that the tablets are not broken or split. Patients should not take tablets that are broken or split. Packages containing broken or split tablets should be returned to the pharmacy for a replacement. Patients should not stop taking birth control tablets unless advised to do so by their health care provider, as they could get pregnant. Patients should talk to their health care provider if they have questions or concerns about their birth control product.

## **Information for health care professionals**

Pfizer Canada Inc. advises health care professionals to remind their patients of the following:

- Check tablets before and after taking them out of the blister package;
- Examine both sides of each tablet thoroughly to determine if the tablet is broken or split. It may not be immediately obvious from looking at the blister package, as the underside of the tablet cannot be seen while in the blister package;
- If a package has a broken or split tablet, return it to the pharmacy for a replacement package.
- Do not consume a tablet if it's broken or split.
- To not stop taking birth control tablets as this will increase the likelihood of pregnancy. For questions or concerns about birth control products, talk to a health care professional, including about alternatives.
- Read the Consumer Information Leaflet included in the ALESSE packaging for detailed instructions in case of a missed dose.

### **Action taken by Health Canada**

Health Canada is communicating this important safety information to health care professionals via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect e-Notice™ email notification system.

Health Canada continues to monitor the situation and the implementation of corrective and preventative actions by the manufacturer.

### **Report health or safety concerns**

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of pregnancy or other serious or unexpected side effects in patients receiving ALESSE 21 and ALESSE 28 should be reported to Pfizer Canada Inc. or Health Canada.

**Pfizer Canada Inc. Contact Information**  
**17300 Trans-Canada Highway**  
**Kirkland, QC**  
**H9J 2M5**

**Telephone:** If you have an inquiry of a medical nature related to ALESSE 21 and ALESSE 28, please contact our Medical Information Group at 1-800-463-6001 (Monday – Friday 9AM-5PM). For all other inquiries, please contact our Customer Service Group at 1-800-387-4974.

To report an adverse event (or suspected side-effect) experienced with a Pfizer medication (prescription, non-prescription or a vaccine) please contact Pfizer at 1-866-723-7111 or by fax at 1-855-242-5652.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Regulatory Operations and Regions Branch  
E-mail: [dcviu\\_uvcm@hc-sc.gc.ca](mailto:dcviu_uvcm@hc-sc.gc.ca)  
Telephone: 1-800-267-9675  
Fax: 1-613-946-5636

Please refer to Pfizer.ca for the ALESSE 21 and ALESSE 28 Product Monograph and for an electronic copy of this communication.

Sincerely,



Vratislav Hadrava M.D., Ph.D.  
Vice-President and Medical Director  
Pfizer Canada Inc.

### References

1. ALESSE (*levonorgestrel and ethinyl estradiol*) Product Monograph. Kirkland (QC). © T.M. Wyeth, Pfizer Canada Inc., Licensee; 2017.