Pfizer Announces Voluntary Nationwide Recall Of Lo/Ovral®-28 And Norgestrel/Ethinyl Estradiol Tablets Due To Possibility Of Inexact Tablet Counts Or Out Of Sequence Tablets

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(BUSINESS WIRE)--Pfizer Inc. announced today that it has voluntarily recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol)Tablets and 14 lots of Norgestrel and Ethinyl Estradiol Tablets (generic)for customers in the U.S. market. An investigation by Pfizer found that some blister packs may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. The cause was identified and corrected immediately.

These products are oral contraceptives indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. These tablets were manufactured and packaged by Pfizer Inc., commercialized by Akrimax Rx Products and labeled under the Akrimax Pharmaceuticals brand. This product is distributed to warehouses, clinics and retail pharmacies nationwide.

As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. These packaging defects do not pose any immediate health risks. However, consumers exposed to affected packaging should begin using a non-hormonal form of contraception immediately. Patients who have the affected product (lot numbers are provided below) should notify their physician and return the product to the pharmacy.

These products are packaged in blister packs containing 21 tablets of active ingredients and seven tablets of inert ingredients. Correct dosing of this product is important in avoiding the associated risks of an unplanned pregnancy.

Correctly Packaged LoOrval Blister Pack Image - www.pfizer.com/img/news/LoOvralCorrectPkg.jpg

Correctly Packaged Norgestrel Image - http://www.pfizer.com/img/news/NorgestrelCorrectPkg.jpg

Any adverse events that may be related to the use of these products should be reported to Akrimax Medical Information at 1-877-509-3935 (8 AM to 7 PM Mon-Fri CST) or to FDA's Med Watch Program either online, by regular mail or by fax.

Online:

www.fda.gov/medwatch/report.htm1

Regular Mail:

Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm2. Mail to the address on the pre-addressed form.

Fax:

1-800-FDA-0178

Pfizer has responded rapidly to ensure that its products continue to meet the company’s high quality standards. The safety of patients who take our medicines is our first priority.

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

Lot numbers of affected packs of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) Tablets and Norgestrel and Ethinyl Estradiol Tablets (generic) follow on the table below:

NDC	Product	Lot	Expiration	Configuration/Count
24090-801-84	LO/OVRAL® 28	E15678	08/31/2013	6 Pilpacks® of 28

tablets each 24090-801-84 LO/OVRAL® 28 E15679 08/31/2013 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 E15686 08/31/2013 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 E15687 01/31/2014 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 E15690 01/31/2014 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 E15698 01/31/2014 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 E15700 02/28/2014 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 E80434 07/31/2013 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 E80438 08/31/2013 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 F36908 02/28/2014 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 F36909 02/28/2014 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 F43915 03/31/2014 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 F43926 03/31/2014 6 Pilpacks® of 28 tablets each 24090-801-84 LO/OVRAL® 28 F43927 03/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg E15677 08/31/2013 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg E15704 01/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg E15706 01/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg E80440 08/31/2013 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F16388 01/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F16390 02/28/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F22132 02/28/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F31330 02/28/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F36911 03/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F36913 03/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F43924 03/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F43925 03/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F43934 03/31/2014 6 Pilpacks® of 28 tablets each 24090-961-84 Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg F53238 03/31/2014 6 Pilpacks® of 28 tablets each

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