Important Safety Information on
Zarontin – Defective Capsules Associated with Reduced Efficacy (Increased Frequency of Seizures)

ERFA
Canada 2012 Inc.

(2016/09/21)

Audience
This notice is addressed to all pharmacists, epilepsy groups and associations.

Key messages

- **Erfa Canada 2012 Inc. and Health Canada have received reports of broken or leaking Zarontin soft gel capsules.**
- **Administration of defective Zarontin soft gel capsules can be associated with a lack of efficacy (increased frequency of seizures).**
- **Pharmacists are reminded to:**
  - **Verify the content of each bottle to make sure that there are no defective capsules.**
  - **Make sure that the product is stored in a controlled temperature and humidity environment.**
- **Patients should inspect their medication and not consume capsules that look defective (e.g., cloudy appearance, broken, sticky, or clumping together). They should return bottles containing defective capsules to the pharmacy where replacement medication can be obtained.**

What is the issue?
Erfa Canada 2012 Inc. and Health Canada have received reports of broken or leaking Zarontin soft gel capsules (DIN 00022799), including reports of patients experiencing a higher frequency of seizures after taking capsules that appeared cloudy, broken, leaking, sticky or clumping together.

Products affected
Zarontin (ethosuximide) 250 mg capsule, **(DIN 00022799, SKU : C33001),** all lots from Erfa Canada 2012 Inc.

Background information
ZARONTIN (ethosuximide) is used for the control of absence (petit mal) epilepsy, which is more common in children than adults. It is taken orally.

The cause of the defective Zarontin capsules is being investigated. Zarontin is available as a soft gel capsule with a gelatin shell and in a syrup formulation. Pharmacists and patients are being reminded that the Zarontin soft gel capsule is very sensitive to humidity. Exposure of the Zarontin capsules to high humidity levels can cause swelling and stickiness of the capsule shells. Swelling of the capsules can stress the integrity of the seals of the capsules, and actions that could have been taken to physically separate capsules that have adhered to each other can also stress the integrity of the seals. Packaging, transportation and storage conditions can impact the integrity of the capsules.

Capsule deterioration, such as cracks or leaks, can reduce the dosage of medicinal ingredient and the effectiveness of the epilepsy medication and potentially lead to a reappearance or increase in absence (petit mal) seizures among patients.

Due to the medical necessity of this drug in the treatment of absence seizures and given that there is a single manufacturer of this drug on the Canadian market and that the syrup formulation is not expected to meet the entire market need for Zarontin, this product is not being recalled. Erfa Canada 2012 Inc. is working with Health Canada to resolve the quality issues identified with Zarontin soft gel capsules.

Information for consumers
Zarontin is a prescription epilepsy drug used to control absence seizures, which are more common in children than adults. Absence seizures last a few seconds and are noticeable by a blank or absent state. Zarontin is available as soft gel capsules or in syrup formulation. The syrup is not affected by this issue.

Patients, parents and caregivers are advised to check their Zarontin capsules. Do not take them if they look unusual (dull, cloudy, sticky, coated with film, or clumping together) or are broken or leaking. Bottles containing defective capsules should be returned to the pharmacy where replacement medication can be obtained.

Zarontin capsules should be stored in a dry place at normal room temperature (15°C- 25°C). Never store in your bathroom or other areas prone to humidity and temperature changes.

Do not stop taking this medication unless advised to do so by your healthcare provider, as suddenly stopping treatment could worsen your condition.

Information for health care professionals
Pharmacists are reminded to:

- Make sure that the product is stored in controlled temperature and humidity conditions.
- Visually inspect the capsules before dispensing them.
- Advise patients to inspect their medication and instruct them not to consume

the capsules that look defective (e.g., cloudy appearance, broken, sticky, or clumping together) and return bottles containing defective capsules to the pharmacy where replacement medication can be obtained.
- Discard bottles containing broken capsules.

Action taken by Health Canada
Health Canada is communicating this important safety information to healthcare 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 is also monitoring the implementation of necessary corrective and preventive actions.

Report health or safety concerns
Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of seizure or other serious or unexpected side effects in patients receiving Zarontin capsule should be reported to **Erfa Canada 2012 Inc.** or Health Canada.

Erfa Canada 2012 Inc.
8250 Decarie, suite 110,
Montreal, Qc, Canada H4P 2P5

To correct your mailing address or fax number, contact Erfa Canada 2012.

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)

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

Regulatory Operations and Regions Branch
E-mail: dcviu_uvcem@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

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