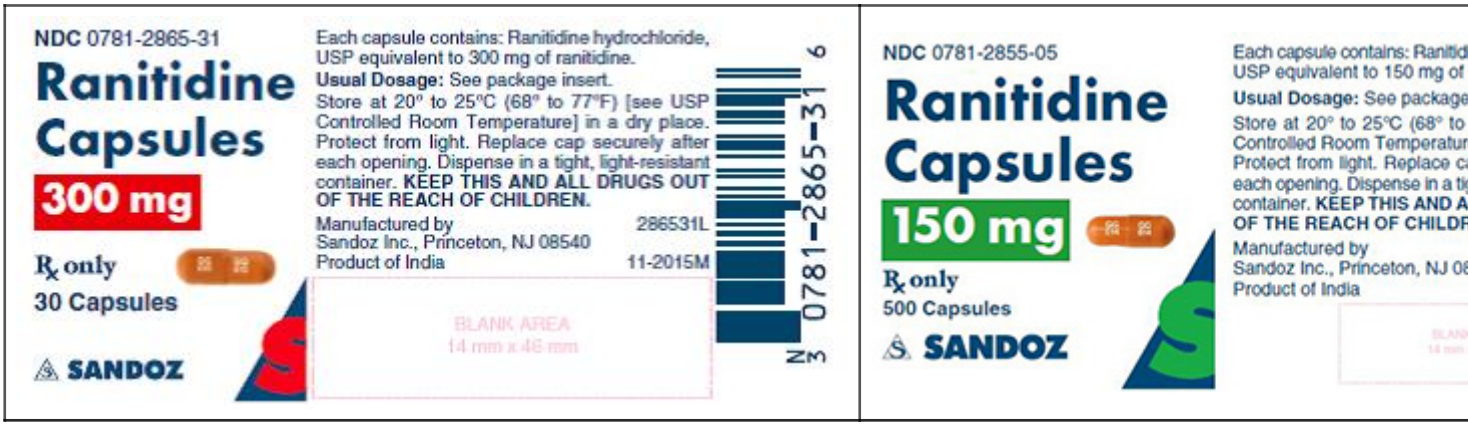
Product Safety Notices [1]

Sandoz Inc. Issues Voluntary Recall of Ranitidine Hydrochloride Capsules 150mg and 300mg Due to an Elevated Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA), in the Product

Sandoz Inc. is voluntarily recalling all quantities and lots within expiry of Ranitidine Hydrochloride Capsules in the US to the consumer level because of confirmed contamination with N-Nitrosodimethylamine (NDMA) above levels established by the FDA in batches of Sandoz Ranitidine Hydrochloride Capsules. To date, Sandoz has not received any reports of adverse events related to use of the product as part of this recall.



PHARMACY ACTION:

Pharmacists are being requested to contact Stericycle directly 1-888-667-1497 Monday – Friday 8:00am – 5:00pm EST to request a recall packet.

Patients are asked to continue taking their medication and speak to their physician on alternative healthcare treatment options. Per U.S. Food and Drug Administration guidance, consumers are asked to continue taking their medication until they speak to their physician or pharmacist on alternate healthcare treatment options. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to

taking or using this drug product. Consumers with questions regarding this recall can contact Sandoz at 1-800-525-8747 option # between 8:30am – 5:00pm Monday – Friday EST or www.us.sandoz.com [2] for more information.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Ranitidine Hydrochloride Capsules is an oral product, indicated for the treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post-operative peptic ulcer, Zollinger-Ellison Syndrome, and other conditions where reduction of gastric secretion and acid output is desirable. The affected Ranitidine Hydrochloride Capsule can be identified by NDC numbers stated on the product label.

The product can be identified by the **NDC Numbers and Lot Numbers Listed Here >>** [3]

Sandoz will be notifying its distributors and customers via overnight mail and via the Sandoz web site, and will arrange for **return** of all recalled products. Wholesalers (direct customers) will be asked to immediately stop distribution and return any stock to Sandoz, and contact the retail pharmacies in their group to do the same. Pharmacies will be asked to immediately stop dispensing Sandoz Ranitidine Hydrochloride Capsules and return remaining stock to Sandoz by contacting Stericycle to request a recall packet. Consumers are asked to continue taking their medication and speak to their physician or pharmacist on alternate healthcare treatment options.

Consumers with questions regarding this recall can contact Sandoz at 1-800-525-8747 option # between 8:30am – 5:00pm Monday – Friday EST or www.us.sandoz.com [4] for more information. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug 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 [5]
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm [6] 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

Sandoz Inc. voluntarily recalls Losartan Potassium and Ezetimibe in prescription drug bottles in the U.S. due to failure to meet child-resistant closure requirements

- *Voluntary recall and notice of corrective action issued because the cap and bottle combination for two medicines distributed in capped bottles in the U.S. does not meet U.S. child-resistant packaging requirements*
- *Particular lots of Ezetimibe 10 mg Tablets and Losartan Potassium 50 mg Tablets packaged in prescription drug bottles are recalled*
- *There are no quality or safety issues with the medicines for their intended use. Patients should immediately secure bottled medicines and their contents to keep out of the sight and reach of children*
- *Patients should continue to use the medicine as prescribed and call 1-800-525-8747 option # to receive free replacement child-resistant bottle caps.*

At Sandoz, we take our responsibility for consumer safety very seriously. As soon as we became aware of the issue, we immediately notified the U.S. Consumer Product Safety Commission (CPSC) and Food and Drug Administration (FDA) that the cap and bottle combination at issue is not compliant for consumer home use. As a result, we are voluntarily recalling and implementing corrective action for these selected lots.

This action is only necessary because the cap and bottle combination does not meet federal standards for child-resistant packaging. **There are no quality or safety issues with the medicines for their intended use.** Patients should continue taking their medicine as directed by their physician, secure the bottled medicines so that they are out of the sight and reach of children, and contact Sandoz at 1-800-525-8747 option # or www.us.sandoz.com [4] for more information and free replacement child-resistant bottle caps.

The products affected by the recall and corrective action notice include particular production lots of the following medicines that have been distributed by **Sandoz** in the U.S. to date:

Ezetimibe: 10mg tablets in 30 and 90 count bottles. National Drug Code (NDC) numbers are # 0781-5690-31 (30 tablets) and # 0781-5690-92 (90 tablets).

Only particular Lot Numbers are affected.

Losartan Potassium: 50mg in 30 count bottles. The affected NDC number is # 0781-5701-31.

Corrective Action

Consumers or pharmacies who have impacted prescription drug bottles with these NDC numbers should contact Sandoz at 1-800-525-8747 option # for free replacement child-resistant bottle caps.

A complete list of the affected lot numbers with expiry dates and package photos is available on the Safety Poster below:

See Safety Notice poster for more information, including Lot Numbers. [7]

Important Correction of Drug Information

Notice to Healthcare Professionals Regarding Sandoz's Bivalirudin for Injection, 250mg/vial

Click here to read [8]

Sandoz recall of select blister packages of products in the U.S. due to packaging requirements for child resistance. Corrective action on packaging required.

- Sandoz Inc has implemented a voluntary recall and notice of corrective action after discovering certain blister card packages distributed in the U.S. do not meet U.S. child-resistant packaging requirements, posing a risk of harm if the tablets are swallowed by children
- Products dispensed in bottles are NOT impacted by this recall
- There are no quality or safety issues with the medicines for their intended use
- Patients should immediately secure impacted blister card packages and their contents to keep out of the sight and reach of children
- Patients should continue to use the medicine as prescribed and call 1-888-NOW NOVA (1-888-669-6682) for important information on corrective actions

See Products affected below:

Risperidone Safety Notice Poster [9]

Additional Products Safety Notice Poster [10]

Ondansetron Safety Notice poster [11]

At Sandoz, we take our responsibility for consumer safety very seriously. The U.S. Consumer Product Safety Commission (CPSC) and Food and Drug Administration (FDA) have been notified that the blister packs for products listed below are not compliant for consumer home use. As a result, we are voluntarily recalling and implementing corrective action for these selected blister packs.

This action is only necessary because the blister packs are not child-resistant. **There are no quality or safety issues with the medicines for their intended use.**

Patients should continue taking their medicine as directed by their physician, secure the affected blister packs so that they are out of the sight and reach of children, and contact Sandoz at 1-888-NOW NOVA (1-888-669-6682) for instructions. Products in bottles are NOT impacted by this recall.

To learn more about the Novartis products affected by this recall and requiring corrective action, please click here [12] to be re-directed to the Novartis website.

Corrective Action

All blister pack configurations (listed below) that are identified as not child-resistant and potentially dispensed for in-home use require corrective action. To secure medicines in blister packs in the homes of consumers, Sandoz will provide child-resistant re-sealable pouches to store your medication. Consumers should immediately secure your blister packs out of the sight and reach of children, and contact us at 1-888-NOVA-NOW to request your pouch.

Here are some easy instructions on how to use your child-resistant, re-sealable pouch.

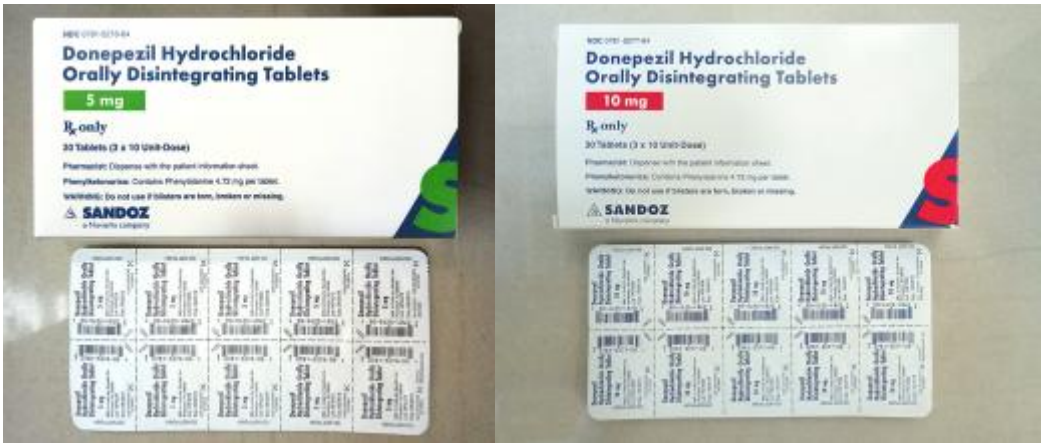
Sandoz Products

The products affected by the recall include production lots of the following medicines that have been distributed by **Sandoz** to date:

Azithromycin: 250mg tablets in 50 count unit dose blister packages.

Azithromycin NDC numbers and Lot numbers [13]
This recall does NOT include Azithromycin 250 mg 6 tablet or 500 mg 3 tablet blister packages, or any product dispensed by pharmacists in bottles.

Donepezil ODT: 5 mg and 10 mg in 30 count hospital unit dose blister packages.



Donepezil NDC numbers and Lot numbers [14]
This does not include any product dispensed by pharmacists in bottles

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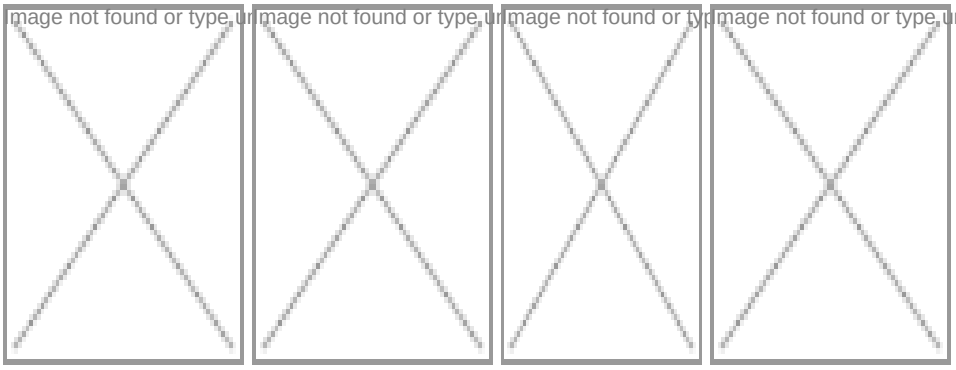
Haloperidol: 0.5mg, 1mg, 2mg, 5mg and 10mg in 100 count hospital unit dose blister

Haloperidol NDC numbers and Lot numbers [15]
This recall does not include any product dispensed by pharmacists in bottles.

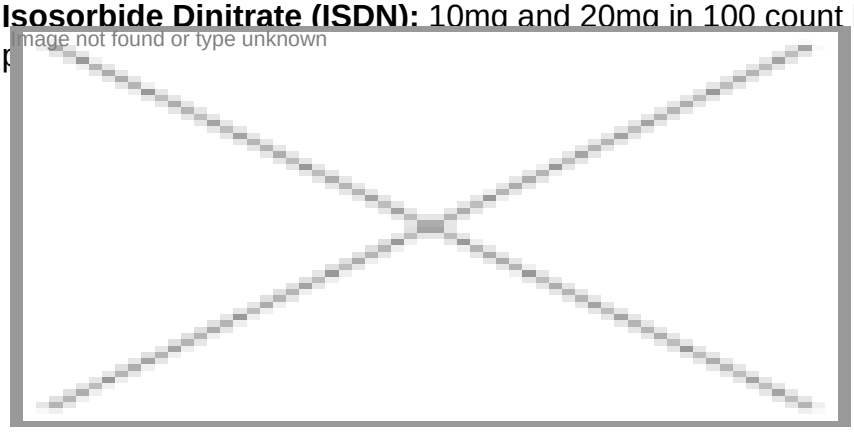
Imipramine: 25mg and 50mg in 100 count hospital unit dose blister packages.



Imipramine NDC numbers and Lot numbers [16]

This recall does not include any product dispensed by pharmacists in bottles.

Isosorbide Dinitrate (ISDN): 10mg and 20mg in 100 count hospital unit dose blister p



Isosorbide Dinitrate (ISDN) NDC numbers and Lot numbers [17]
This recall does not include any product dispensed by pharmacists in bottles.

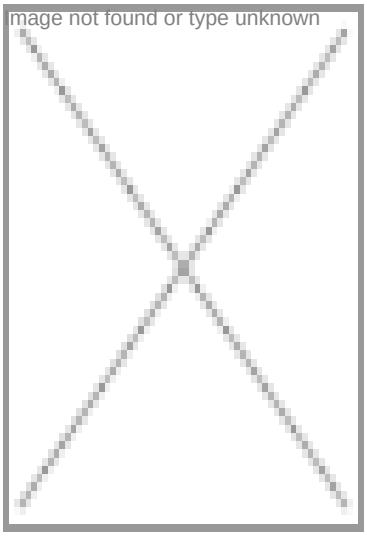
Naratriptan Tablets: 2.5 mg in 9 count hospital unit dose blister packages.

Naratriptan NDC numbers and Lot numbers [18]
This recall does not include any product dispensed by pharmacists in bottles.

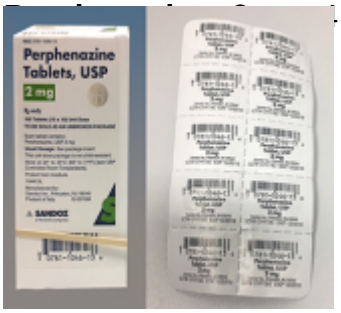
Ondansetron ODT: 4mg and 8mg Orally Disintegrating Tablets (ODT).

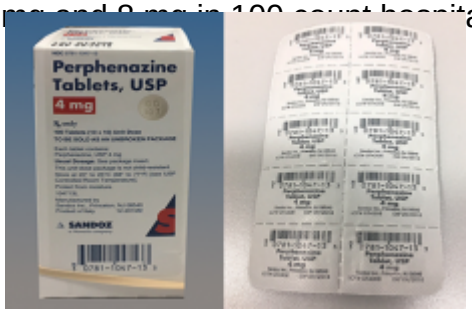
Ondansetron ODT NDC numbers and Lot numbers [19]
This recall does not include any product dispensed by pharmacists in bottles.

Ondansetron: 8mg tablets in blister packs of 3 tablets.



Ondansetron Tablets NDC numbers and Lot numbers [20]
This recall does not include Ondansetron 4mg tablets in unit dose blister packs of 3 tablets or Ondansetron tablets dispensed by pharmacists in bottles.





Perphenazine NDC numbers and Lot numbers [21]
This recall does not include any product dispensed by pharmacists in bottles.

Risperidone ODT: 0.5mg, 1mg, 2mg, 3mg and 4mg Orally Disintegrating Tablets (ODT) in 28 count blister packages.

Risperidone NDC numbers and Lot numbers [22]
This recall does not include any product dispensed by pharmacists in bottles.

Consumers or pharmacies who have impacted blister packaged products with these NDC numbers in their homes or pharmacies should contact us at 1-888-NOW-NOVA or 1-888-669-6682.

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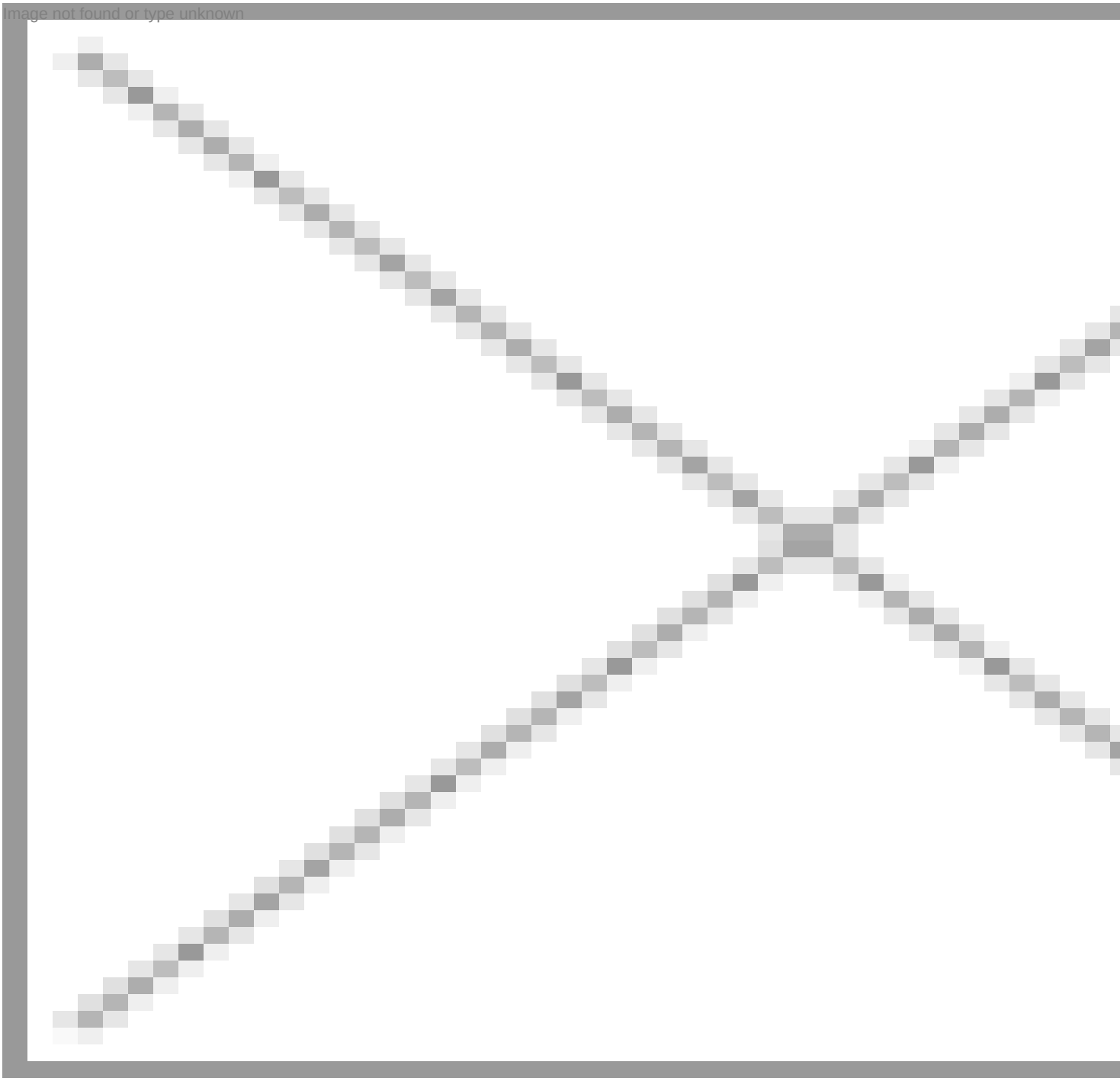

Document:
Sandoz DHCP-Bivalirudin for Inj leaflet error_Mar2019.pdf [8]
Teaser:
At Sandoz, patient safety comes first. See current product recalls.
Accordion Type:
- Collapsible

Source URL: https://www.us.sandoz.com/patients-customers/product-safety-notices

Links
[1] https://www.us.sandoz.com/patients-customers/product-safety-notices
[2] http://www.us.sandoz.com
[3] https://www.us.sandoz.com/sites/www.us.sandoz.com/files/Ranitidine%20AREV2_Lot%20Numbers.pdf
[4] https://www.us.sandoz.com/
[5] http://www.fda.gov/MedWatch/report.htm

[6] http://www.fda.gov/MedWatch/getforms.htm
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