



QUESTIONS & ANSWERS

McNeil Consumer Healthcare Canada Announces Voluntary Recall of all lots and flavours of ROLAIDS® Ultra Strength SoftChews® and ROLAIDS® Ultra Strength SoftChews® plus Gas Relief Sold in Canada

1. Why is McNeil Canada initiating this recall?

In consultation with the Health Canada, McNeil Consumer Healthcare, Division of Johnson & Johnson Inc is voluntarily recalling all lots and flavours of *ROLAIDS® Ultra Strength SoftChews® and ROLAIDS® Ultra Strength SoftChews® plus Gas* (full product details below) distributed in Canada.

McNeil is taking this action following some consumer reports of foreign materials in the product, including metal and wood particles.

While the risk of serious adverse health consequences is remote, McNeil Consumer Healthcare advises consumers who have purchased these recalled products to discontinue use.

2. What products are included in the recall?

All lots and flavours of ROLAIDS® SoftChews® products.

PRODUCT RECALL INFORMATION

All lot numbers and all flavors of ROLAIDS® SoftChews® are affected by this recall. The UPC code is located on the back panel of the product package.

DESCRIPTION
ROLAIDS® Ultra Strength SoftChews® Plus Gas Relief Tropical Fruit 36's
ROLAIDS® Ultra Strength SoftChews® Plus Gas Relief Tropical Fruit 24's
ROLAIDS® Ultra Strength SoftChews® Cherry 6's
ROLAIDS® Ultra Strength SoftChews® Vanilla 6's
ROLAIDS® Ultra Strength SoftChews® Cherry 42's
ROLAIDS® Ultra Strength SoftChews® Cherry 36's
ROLAIDS® Ultra Strength SoftChews® Vanilla 42's
ROLAIDS® Ultra Strength SoftChews® Vanilla 36's

3. What is the source of the “foreign materials”?

The company’s investigation has determined that the materials were potentially introduced into the product during the manufacturing process at a third party manufacturer. While our investigation is ongoing we have suspended production of all ROLAIDS® SoftChews® products and will not restart production until corrective actions have been implemented.

4. Are there any consumer safety concerns related to the reason for the recall?

While the risk of serious adverse health consequences is remote, McNeil Consumer Healthcare advises consumers who have purchased these recalled products to discontinue use. Consumers who have medical concerns or questions should contact their healthcare provider.

5. Have there been any adverse events (issues or injuries) related to this recall reported?

As of the date of the recall, McNeil Consumer Healthcare in the US has had a small number of adverse reports associated with the product being recalled; vomiting, gum and tooth injury, and abnormal taste.

The Canadian product is produced in the same manufacturing site as the US product however, as of the date of this recall McNeil Consumer Healthcare Canada has not had any adverse events reported related to foreign material in the product affected by this recall.

While the risk of serious adverse health consequences is remote, McNeil Consumer Healthcare advises consumers who have purchased these recalled products to discontinue use. Consumers who have medical concerns or questions should contact their healthcare provider.

6. Can I continue to use the product that I have in my possession?

While the risk of serious adverse health consequences is remote, McNeil Consumer Healthcare advises consumers who have purchased these recalled products to discontinue use. Consumers who have medical concerns or questions should contact their healthcare provider.

7. What product do you recommend I use instead of the ROLAIDS® SoftChews®?

If you would like assistance in selecting an alternate product you should seek the advice of a pharmacist or physician.

8. How should I dispose of product that I have in my possession:

We recommend the disposal of medicines in an environmentally safe manner as defined by the laws of individual provinces and local municipalities. We encourage consumers to return unused products to pharmacies or to local municipal waste disposal depots (where available) for proper disposal. For more information on the Proper Use and Disposal of Medication visit Health Canada at www.hc-sc.gc.ca (Healthy Living > It's Your Health > Medical).

9. Where do I call if I want more information or to request a refund?

Please call our consumer contact center at : 1-888-222-6036

10. Can I request a product reimbursement on line?

Yes please visit www.injcanada.com and go to the contact us page. On the contact us page, click on the "contact us by email" link – there are complete instructions to submit for your reimbursement on line.