January 6, 2023, Warren, NJ

Haleon Contact Center: 1-800-88-ADVIL

Haleon, the makers of Advil® products, is issuing this public notification to alert consumers of a defect of certain peel-back labels that may render some critical safety information unreadable.

Always read the label before you take Advil or any other nonprescription medicine. <u>If any</u> <u>portion of the label is torn, smudged or otherwise unreadable, please find a complete</u> <u>version with all current information at www.advil.com, or call the Haleon Contact Center</u> <u>at 1.800.88.ADVIL (1.800.881.3845).</u>

A list of impacted lots of Advil products is provided below. A voluntary wholesale level recall of these lots was initiated on December 6th, 2022. This notification is to inform consumers if any assistance needed if they come across defective labels. Please note that this issue only impacts the labels. There is nothing wrong with the products themselves, which are safe to take when used as directed.:

Product	NDA#	Lot Number	Expiry Date
Advil [®] Tablets 360CT (CLUB)	018989	EJ2218, EJ2219, EJ2220	9/30/2023
Advil [®] Tablets 200ct EZ Open	018989	953D	5/31/2025
Advil [®] Liqui-Gels 200ct	020402	R94065	02/29/2024
Advil [®] Liqui-Gels Minis 200ct	020402	R93517, R94072, R94073 T00655	02/29/2024 03/31/2025

Image: Advil Tablets, example of torn label (same bottle, different angles)



Image: Advil Liqui-Gels, example of torn label (same bottle, different angles)



Image: Advil Tablets, example of an intact label

	-	
Drag Facts (continued) Wornings Margi skit Amarika ingo same a severa skitup matter samale is a severa skitup Severa is a severa severa severa skitup matter samale is a severa skitup Severa is a severa severa is a several Severa is a severa severa is a several Severa is a severa severa is a several Severa is a severa severa severa severa severa severa severa severa severa Severa is a severa	Day Fracts (contraved) Hist is fracts interest as a more to assess young signly to the total assess (see to another total assess) Hist is fracts interest as a more total assess (see to another total asses) Hist is fracts interest as a more total assess (see to another total asses) Hist is fracts interest as a more total assess (see to another total asses) Hist is fracts interest as a more total assess (see to another total asses) Hist is fracts interest and assess (see to another total asses) Hist is fracts interest and assess interest assess (see to another total asses) Hist is another total assess interest assess Hist assess interest assess interest assess interest assess interest assess Hist assess interest assess interest assess interest assess interest assess Hist assess interest assess interest assess interest	During Facebra (ECONDENCION) Hyperball of learned meetings, can a health antibication of the second instance in the second carling that hand it without an observation, and an exact of an early of a stability of the second instance in the second meeting of an early of a stability of the second of the second of the second carling of the second of the second of the second of the instance second instances second instances second instances second instances and the second of the 1 table second of the instances second instances second insta

Representative Product labels:

ADVIL® TABLETS 200ct EZ Open (front)



ADVIL® TABLETS 360CT (CLUB, front)



ADVIL® LIQUI-GELS 200CT (front)



ADVIL® LIQUI-GELS MINIS 200CT (front)



As of December 19, 2022, Haleon has not received any reports of adverse events related to this issue.

The product is used as a pain reliever and fever reducer and is packaged as follows:

Advil® Tablets 360ct (CLUB): NDC #0573-0154-60

- o 1 plastic bottle with 360 tablets, 35 bottles in a cardboard shipper
- Advil[®] Tablets 200ct EZ Open: NDC #0573-0154-21
 - o 1 plastic bottle with 200 tablets; 12 bottles in a cardboard shipper
- Advil[®] Liqui-Gels 200ct bottle: NDC #0573-0169-49
 - \circ 1 plastic bottle with 200 liqui-gels; 12 bottles in a cardboard shipper
- Advil[®] Liqui-Gel Minis 200ct bottle: NDC #0573-1769-13
 - 0 1 plastic bottle with 200 liqui-gels; 12 bottles in a cardboard shipper

The product can be identified by locating the lot information as represented in the images, below:



The lot number can also be found on the shipping case labels:



Consumers with questions can contact Haleon by phone: **1-800-88-ADVIL** or email: **<u>mystory.us@haleon.com</u>**, Monday – Friday, 8:00am – 6:00pm EST. 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**: <u>www.fda.gov/medwatch/report.htm</u>¹
- **Regular Mail or Fax**: Download form <u>www.fda.gov/MedWatch/getforms.htm</u>² 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 notice is being issued with the knowledge of the U.S. Food and Drug Administration.