

SAFETY NOTICE

Zofran® ODT (ondansetron) 4 mg and 8 mg Orally Disintegrating Tablets (ODT)



Novartis Pharmaceuticals Corporation has determined that blister packs of Zofran ODT (ondansetron) 4 mg and 8 mg Orally Disintegrating Tablets (ODT) distributed in the U.S. are not child-resistant, posing a risk of harm if the tablets are swallowed by children.

These products are voluntarily recalled for corrective action because the blister packs are not child-resistant.

There are no quality or safety issues with the medication itself for its intended use.

This notification applies only to the following NDC numbers with corresponding lot numbers and expiration dates.

Product Description	NDC on Carton	NDC on Blister Pack	Lot Number	Expiry Date
Zofran ODT 4 mg	0078-0679-19	0078-0679-61	1657088	Dec 2019
Zofran ODT 8 mg	0078-0680-19	0078-0680-61	1641546	Oct 2019

What do patients need to do?

1. Immediately secure this medicine so that it is out of the sight and reach of children.
2. Continue taking your Zofran tablets as prescribed, as there are no safety or quality issues with the medicine itself.
3. Please contact Novartis Pharmaceuticals Corporation at **888-NOW-NOVA (888-669-6682)** for important information on corrective action for your Zofran blister packs.

We appreciate your immediate attention and cooperation and apologize for this situation.

Please report any adverse events by calling Novartis at **888-NOW-NOVA (888-669-6682)** or by emailing Novartis at usdrugsafety.operations@novartis.com. Adverse events can also be reported to FDA online at www.fda.gov/medwatch/report.htm.