SAFETY NOTICE

ENTRESTO® (sacubitril / valsartan) Tablets in Blister Packs

Novartis Pharmaceuticals Corporation has determined that the 100 count Hospital Unit Dose BLISTER PACKS of Entresto (sacubitril/valsartan) Tablets 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 concerns with the medicines for their intended use.

Blister packs were intended for institutional (i.e., hospital) use only. A small number of blister packs may have been dispensed for in-home use in the U.S. market.

Entresto Tablets in bottles are not affected by this recall.

This notification applies ONLY to the NDC and lot numbers listed below

Product Description	NDC Number on Carton	NDC Number on Blister Pack	Lot Number	Expiration Date
Entresto FCT 24 mg/26 mg HUD Blister Pack	0078-0659-35	0078-0659-61	FX000005 FX000004 FX000003 F0010 F0009 F0007	Apr 2020 Apr 2020 Sep 2019 Nov 2018 Aug 2018 Jul 2018
Entresto FCT 49 mg/51 mg HUD Blister Pack	0078-0777-35	0078-0777-61	FX000001 F0006 F0005 F0004	Dec 2019 Oct 2019 Aug 2019 Oct 2018
Entresto FCT 97 mg/103 mg HUD Blister Pack	0078-0696-35	0078-0696-61	FX000002 F0007 F0006 F0005 F0004	Mar 2020 Feb 2020 Dec 2019 Dec 2018 Oct 2018

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 medicine as prescribed, as there are no safety or quality issues with the medicine itself.**
3. **Please contact Novartis Pharmaceutical Corporation at 888-NOW-NOVA (888-669-6682) for important information on corrective action for your Entresto 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.

Post until November 6, 2018
In cooperation with the U.S. Consumer Product Safety Commission

NOVARTIS