

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a nationwide recall of *the below seven (7) lots* of **Clonidine Transdermal System, USP, 0.1, 0.2 and 0.3 mg/day** to the **RETAIL LEVEL**. The product in this recall is distributed under the Actavis Pharma Inc. label. The reason for the recall is due to use of an unapproved raw material (CoTran 9728 Membrane) in the manufacture of Clonidine Transdermal System, USP 0.1, 0.2, 0.3 mg/day. The primary health concern associated with this recall is due to a lack of extractable and leachable data for the unapproved raw material to establish safety of the drug product. Teva's toxicological evaluation and health hazard assessment concluded that the severity of the hazard was assessed as no adverse health consequences and the overall risk of harm in the patient population is considered as not applicable.

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Clonidine Transdermal System, USP 0.1 mg/day

Carton NDC	Pouch NDC	Lot #	Exp. Date	Size
0591-3508-04	0591-3508-54	100060315	04/2026	4 pouch/carton
0591-3508-04	0591-3508-54	100068644	01/2027	4 pouch/carton

Clonidine Transdermal System, USP 0.2 mg/day

Carton NDC	Pouch NDC	Lot #	Exp. Date	Size
0591-3509-04	0591-3509-54	100060002	07/2026	4 pouch/carton
0591-3509-04	0591-3509-54	100066802	05/2027	4 pouch/carton

Clonidine Transdermal System, USP 0.3 mg/day

Carton NDC	Pouch NDC	Lot #	Exp. Date	Size
0591-3510-04	0591-3510-54	100053892	04/2026	4 pouch/carton
0591-3510-04	0591-3510-54	100057899	05/2026	4 pouch/carton
0591-3510-04	0591-3510-54	100062704	02/2027	4 pouch/carton