

Novartis – Recall of Sandimmune® (cyclosporine) and Neoral® (cyclosporine)

- On March 18, 2020, [Novartis announced](#) a recall of some lots of [Sandimmune \(cyclosporine\)](#) and [Neoral \(cyclosporine\)](#) 100 mg soft gelatin capsule prescription drug blister packages because the drug packaging is not child resistant as required by the Poison Prevention Packaging Act, posing a risk of poisoning if the contents are swallowed by young children.
- This recall is not a result of any quality or efficacy issues with the medicines for their intended use.
- Only 100 mg doses of these medications with the following NDC and lot numbers and expiration dates are included in this recall:

Product Description	NDC#	Lot# (Expiration Date)
Sandimmune (cyclosporine) 100 mg soft gelatin capsules; blister packs of 30 capsules	0078-0241-15 (carton); 0078-0241-61 (blister pack)	APCA136 (9/2020); APCA339 (2/2021); APCA793 (1/2022); APCC238 (7/2022)
Neoral (cyclosporine) 100 mg soft gelatin capsules, modified; blister packs of 30 capsules	0078-0248-15 (carton); 0078-0248-61 (blister pack)	APCA437 (7/2020); APCA979 (3/2021)

- Sandimmune is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants. The drug may also be used in the treatment of chronic rejection in patients previously treated with other immunosuppressive agents.
- Neoral is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants. It is also indicated for the treatment of patients with severe active, rheumatoid arthritis where the disease has not adequately responded to methotrexate and for the treatment of adult, nonimmunocompromised patients with severe, recalcitrant, plaque psoriasis who have failed to respond, have a contraindication or cannot tolerate other therapies.
- Consumers should immediately secure the product out of the sight and reach of children and contact Novartis to request a free child-resistant pouch in which to store the blister package medications.
- Consumers can continue to use the medication as directed. The child-resistant pouches should be used to store these medications until new child-resistant blister packaging is available.

- Contact Novartis by phone at **866-629-6182** or by email at **Novartis5060@stericycle.com** for further information about this recall.



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