NOVARTIS

Novartis Pharmaceuticals Corporation corrective action for certain blister packages of SANDIMMUNE® and NEORAL® 100-mg soft gelatin capsules in the US due to failure to meet child-resistant packaging requirements

Mar 18, 2020

- *Consumer Product Safety Commission-approved corrective action issued after Novartis identified that certain blister card packages of SANDIMMUNE® (cyclosporine capsules, USP) 100-mg soft gelatin capsules and NEORAL® (cyclosporine capsules, USP) MODIFIED 100-mg soft gelatin capsules distributed in the US do not meet child-resistant packaging requirements*
- *All lots within expiry of 30-count SANDIMMUNE (cyclosporine capsules, USP) 100-mg soft gelatin capsules and NEORAL (cyclosporine capsules, USP) MODIFIED 100-mg soft gelatin capsules in blister card packages are impacted by this corrective action*
- *SANDIMMUNE (cyclosporine capsules, USP) 25-mg soft gelatin capsules and NEORAL (cyclosporine capsules, USP) MODIFIED 25-mg soft gelatin capsules are NOT included in this corrective action*
- *There are no quality or efficacy issues with the medicines for their intended use*
- *Patients should continue to use the medicine as prescribed, immediately secure impacted blister card packages and their contents to keep out of the sight and reach of children, and contact Novartis at 1-866-629-6182 or Novartis5060@stericycle.com to receive a resealable child-resistant pouch free-of-charge*

East Hanover, March 18, 2020— Novartis Pharmaceuticals Corporation (Novartis) announced a Consumer Product Safety Commission (CPSC)-approved corrective action plan after identifying certain blister card packages (blister packs) of SANDIMMUNE (cyclosporine capsules, USP) 100-mg soft gelatin capsules and NEORAL (cyclosporine capsules, USP) MODIFIED 100-mg soft gelatin capsules distributed in the US do not meet child-resistant packaging requirements, posing a potential risk of harm if children open the package and swallow the medicine.

At Novartis, we take our responsibility for consumer safety very seriously. As soon as we became aware that these blister packs do not meet federal standards for child-resistant packaging, we promptly notified the CPSC and the Food and Drug Administration (FDA) and have been working closely with the CPSC to remedy the packaging issue and ensure continuity of treatment. An appropriate solution was identified in cooperation with the CPSC.

This action is only necessary because the blister packs at issue do not meet US child-resistant packaging requirements. **There are no quality or efficacy issues with the medicines for their intended use**. Patients should continue to use the medicine as prescribed, immediately secure impacted blister card packages and their contents to keep out of the sight and reach of children, and contact Novartis at 1-866-629-6182 or Novartis5060@stericycle.com to receive a resealable child-resistant pouch free-of-charge.

To avoid a drug shortage, as an interim measure until child-resistant packaging is available, Novartis is providing child-resistant, resealable pouches to patients with the affected medicines in their homes and to

pharmacies to use in dispensing current inventory and future shipments of SANDIMMUNE and NEORAL soft gelatin capsules 100-mg. We are also developing new packaging to meet CPSC child-resistant packaging requirements. Novartis is working with urgency to ensure patients will have access to all impacted products while we work to resolve this situation.

The products affected by the corrective action include production lots of the following medicines in blister packs that have been distributed by Novartis in the US to date:

SANDIMMUNE (cyclosporine capsules, USP) 100-mg soft gelatin capsules:
100-mg 30-count blister packs and liquid filled single capsule blister packs. The affected National Drug Code (NDC) numbers for blister packs are #0078-0241-15 and #0078-0241-61.

NEORAL (cyclosporine capsules, USP) MODIFIED 100-mg soft gelatin capsules: 100-mg 30 count blister pack and liquid filled single capsule blister packs. The affected NDC numbers for blister packs are #0078-0248-15 and #0078-0248-61.

The affected lot numbers and NDC with expiry dates and package photos are available at:
https://www.pharma.us.novartis.com/news/statements/corrective-action-certain-100-mg-sandimmune-and-neoral-blister-packages-us

SANDIMMUNE (cyclosporine capsules, USP) 25-mg soft gelatin capsules and NEORAL (cyclosporine capsules, USP) MODIFIED 25-mg soft gelatin capsules 30-count packages are NOT included in this corrective action.

Consumers or pharmacies who have impacted blister packs with these NDC numbers in their homes or pharmacies should contact Novartis at 1-866-629-6182 or Novartis5060@stericycle.com for resealable children-resistant pouches and important instructions on corrective actions. For more information on Novartis products, please find details on our website: https://www.pharma.us.novartis.com.

About Novartis
Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of Novartis – is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis employs about 15,000 people in the United States. For more information, please visit https://www.novartis.com/us-en.

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