Updated packaging now available for SANDIMMUNE® 100 mg blister packages

Nov 30, 2021

- *Packaging of SANDIMMUNE® (cyclosporine capsules, USP) 100 mg soft gelatin capsules 30-count blister packs updated to meet federal child-resistant packaging requirements*
- *Update implemented in cooperation with the US Consumer Product Safety Commission (CPSC) as part of previously announced CPSC-approved corrective action plan that concerned packaging only*

Novartis Pharmaceuticals Corporation (Novartis) announced new packaging is now available for 30-count blister card packages (blister packs) of SANDIMMUNE® (cyclosporine capsules, USP) 100 mg soft gelatin capsules. The updated packaging was implemented in cooperation with the US Consumer Product Safety Commission (CPSC) to ensure it meets federal child-resistant packaging requirements, as part of a previously announced CPSC-approved corrective action plan for SANDIMMUNE 100 mg soft gelatin capsules 30-count blister packs distributed in the US.

There were no quality or efficacy issues with the medicine for its intended use; the action concerned packaging only. Novartis takes its responsibility for consumer safety very seriously and made the following package design changes to ensure the blister packs of SANDIMMUNE 100 mg soft gelatin capsules meet federal child-resistant packaging requirements.

- Foil thickness increased to improve the toughness, puncture-resistance, and peel-strength properties of the blister packs.
- Blister card size increased to incorporate a larger seal area.
- Secondary packaging (folding carton) enlarged to fit the larger blister cards inside.
- Blister perforations removed to eliminate the potential of a child peeling back the blister from the perforation.
- Circular thumb-notch cut-outs removed from the blister cards to increase the difficulty of a child penetrating the blister card at these locations.
- Scissor icon and dotted line added to the blister card artwork to direct the (adult) patient to cut the foil open along this line to remove the capsule.
- Patient directions for using the blister card updated on the folding carton box artwork, based on the package design changes.

As soon as the company became aware that these blister packs posed a potential risk of harm if children opened the package and swallowed the medicine, Novartis promptly notified the CPSC and the US Food and Drug Administration (FDA) and has been working closely with the CPSC to remedy the packaging and ensure continuity of treatment.

Patients should ask their healthcare professional if they have questions about the new packaging. Healthcare professionals with questions should contact Novartis Medical Information at 1-888-669-6682.

The previously announced CPSC-approved corrective action plan included production lots of SANDIMMUNE 100 mg 30-count blister packs and liquid filled single capsule blister packs, and NEORAL® (cyclosporine

capsules, USP) MODIFIED 100 mg soft gelatin capsules 30-count blister packs, within expiry distributed in the US. Information on this corrective action, and affected lot numbers and NDC with expiry dates and package photos, are available at: https://www.novartis.com/us-en/news/statements/corrective-action-certain-100-mg-sandimmune-and-neoral-blister-packages-us. SANDIMMMUNE (cyclosporine capsules, USP) 25 mg soft gelatin capsules and NEORAL (cyclosporine capsules, USP) MODIFIED 25-mg soft gelatin capsules 30-count packages were not included in the corrective action, nor were SANDIMMUNE oral solution in bottles and SANDIMMUNE concentrate for infusion in ampules.

An update on new packaging for 30-count blister packs of NEORAL 100 mg soft gelatin capsules will be shared once it is available. Patients who still have SANDIMMUNE 100 mg soft gelatin capsules or NEORAL MODIFIED 100-mg soft gelatin capsules affected by this action in their possession can request a free child-resistant pouch by calling toll free 1-866-629-6182 between the hours of 8 a.m.-8 p.m. ET or by sending an email to Novartis5060@stericycle.com.

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