Product News

Carmex Winter Mint Lip Balm Click Stick

Carma Laboratories, Inc, introduces limited-edition Carmex Winter Mint Lip Balm Click Sticks. The new seasonal flavor, which comes in convenient click sticks that glide on lips easily, is available to consumers as part of specially marked 2-pack and 4-pack promotions. Both offers combine the Carmex Original Lip Balm Click Stick or Carmex Original Lip Balm Tube with a bonus Winter Mint seasonal stick and will be available at select retailers while supplies last. For more information, visit www.mycarmex.com.

Daytrana Patch

The US Food and Drug Administration (FDA) has added a new warning of chemical leukoderma to the drug label for the Daytrana patch (methylphenidate transdermal system)(Noven Therapeutics, LLC), which treats attention deficit hyperactivity disorder in children and adolescents. Chemical leukoderma is a condition that causes loss of skin color due to repeated exposure to specific chemical compounds. The areas of skin color loss described with the Daytrana patch ranged up to 8 inches in diameter. The FDA recommends that patients or their caregivers should watch for new areas of lighter skin, especially under the drug patch, and immediately report these changes to a health care professional. For more information, visit www.fda.gov/MedWatch.

Enstilar Foam

LEO Pharma Inc announces US Food and Drug Administration approval of Enstilar (calcipotriene and metamethasone dipropionate) Foam 0.005%/0.064% for topical treatment of plaque psoriasis in patients aged 18 years and older. Enstilar is an alcohol-free foam formulation in a pressurized spray can that allows application across large body areas of plaque psoriasis and should be applied to affected areas once daily for up to 4 weeks. The approval was based on pivotal clinical trial data at week 4 that also showed patients using Enstilar achieved efficacy as early as week 2. For more information, visit www.enstilar.com.

IMLYGIC

Amgen Inc announces that the US Food and Drug Administration has approved the Biologics License Application for IMLYGIC (talimogene laherparepvec), a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. IMLYGIC is the first oncolytic viral therapy approved based on therapeutic benefit demonstrated in a pivotal study, and variability of dosing from patient to patient is expected. IMLYGIC has not been shown to improve overall survival or have an effect on visceral metastases, and treatment is contraindicated in immunocompromised patients. For more information, visit www.imlygic.com.

Juvéderm Ultra XC

Allergan, Inc announces US Food and Drug Administration approval to market Juvéderm Ultra XC gel for injection into the lips and perioral area for lip augmentation in patients over the age of 21 years. Juvéderm Ultra XC is a smooth gel formulation made up of a modified form of hyaluronic acid, a naturally occurring sugar found in the human body whose role is to deliver nutrients and help the skin retain its natural moisture and softness. The gel formulation also contains a small amount of lidocaine, which improves the comfort of the injection. For more information, visit www.juvederm.com.

Opdivo + Yervoy Regimen

Bristol-Myers Squibb Company obtains US Food and Drug Administration approval for the Opdivo (nivolumab) + Yervoy (ipilimumab) regimen in BRAF V600 wild-type unresectable or metastatic melanoma. The approval, which is based on data from a pivotal study, marks the first approval of a regimen of 2 immuno-oncology agents in cancer. This indication is approved under accelerated approval based on tumor response rate and durability of response. Opdivo and Yervoy are immune checkpoint inhibitors that target separate, distinct, and complementary checkpoint pathways (PD-1 and CTLA-4). The mechanism of action involves dual immune checkpoint inhibition resulting in increased antitumor activity. For more information, visit www.bms.com.

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