

IMPORTANT SAFETY INFORMATION FOR BELOTERO BALANCE® DERMAL FILLER

Indication: BELOTERO BALANCE® is FDA-approved for injection into the mid-to-deep dermis for correction of moderate-to-severe facial wrinkles and folds, such as nasolabial folds.

Contraindications: BELOTERO BALANCE® should not be used in patients with severe allergies manifested by a history of anaphylaxis, with a history or presence of multiple severe allergies. BELOTERO BALANCE® contains a trace amount of gram-positive bacterial proteins, and is contraindicated in patients with a history of allergies to such material. BELOTERO BALANCE® must not be implanted into blood vessels.

Warnings: Use of BELOTERO BALANCE® at specific sites in which an active inflammatory process (skin eruptions such as cold sores, cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled. BELOTERO BALANCE® must not be injected into blood vessels of any size. Introduction of BELOTERO BALANCE® into the vasculature may occlude the vessels and can cause infarction of overlying tissue or embolization with resultant necrosis of potentially large areas of distant tissue such as the lip or the nose. Injection site responses to BELOTERO BALANCE® have been observed, consisting mainly of short-term inflammatory symptoms starting early after treatment and with 7 days duration or less.

Precautions: The safety or effectiveness of BELOTERO BALANCE® for the treatment of dermal contour defects other than nasolabial folds, such as use in the lips, has not been established in controlled clinical studies. The safety of BELOTERO BALANCE® for use during pregnancy, in breastfeeding females, or in patients under 21 years has not been established. As with all transcutaneous procedures, BELOTERO BALANCE® injection carries a risk of infection. Patients who are using substances that reduce coagulation, such as aspirin, non-steroidal anti-inflammatory drugs, and warfarin may, as with any injection, experience increased bruising or bleeding at injection sites. Patients should inform their physicians if they are taking such substances. Laser treatment, chemical peeling, or any other procedure based on active dermal response performed after treatment with BELOTERO BALANCE® may increase the risk of an inflammatory reaction at the injection site. Similarly, the administration of BELOTERO BALANCE® before the skin has healed completely after such a procedure may also increase the risk of inflammatory reactions. Exposure of the treated area to excessive sun, UV lamp exposure, and extreme cold weather should be minimized until any initial swelling and redness have resolved and puncture sites have healed.

Adverse Events: The most common side effects seen after injection were swelling, bruising, redness, and hardening that resolve within one week. More rare side effects may include swelling that lasts longer, unevenness or firmness in the area injected, and as with any injection, there may be a risk of infection.

Important: For full safety information, please visit www.Belotero.com or call Merz Aesthetics Customer Service at 866-862-1211

Caution: Rx only