

What is BELOTERO BALANCE?

BELOTERO BALANCE[®] is a prescription injection that is approved to temporarily smooth out and fill in moderate-to-severe nasolabial folds (the folds or wrinkles that go from the side of the nose to the corner of the mouth).

IMPORTANT SAFETY INFORMATION FOR BELOTERO BALANCE[®]

Who should not use BELOTERO BALANCE?

BELOTERO BALANCE should not be used in patients with a history of or presence of multiple or severe allergies, including those with a history of anaphylaxis. BELOTERO BALANCE should not be used in patients with allergies to gram-positive bacterial proteins.

What is the most important information I should know about BELOTERO BALANCE?

As with all events that involve an injection through the skin, there is a risk of infection. Laser treatments or chemical peels or any other treatments that affect the skin can increase the risk of infection. Do not use BELOTERO BALANCE if you have a skin inflammation or a skin infection. Do not use until the infection is healed.

Patients getting BELOTERO BALANCE may have an injection site reaction. These reactions can include inflammation and usually last less than seven days.

For approximately 24 hours after treatment, avoid:

- strenuous activity
- extensive sun or heat exposure
- aspirin or non-steroidal anti-inflammatory drugs
- alcoholic beverages

Exposure to any of the above can cause temporary redness, swelling, and/or itching at the injection site.

It is not known how BELOTERO BALANCE will work in areas of the face other than the smile lines.

It is not known how BELOTERO BALANCE will work in women who are pregnant or breastfeeding or people who are less than 21 years of age.

What should I tell my doctor before injections with BELOTERO BALANCE?

Tell your doctor if you are taking medicines that affect blood clotting, like aspirin, an NSAID or warfarin. These medicines may put you at an increased risk of bruising or bleeding at the treatment site.

Tell your doctor if you have a skin reaction like cold sores, cysts, pimples, rashes, hives, or an infection. Treatment with BELOTERO BALANCE should be delayed until the reaction goes away.

Tell your doctor if you are taking medicines that affect your immune system.

What are the most common adverse events seen with BELOTERO BALANCE?

The most common local side effects seen with BELOTERO BALANCE were swelling, bruising, redness, hardening of the skin, pain, altered color, or itching. Other side effects that have occurred with BELOTERO BALANCE include headache, swelling of the side of the nose, moderate cold sore, lip numbness, and lip dryness. Side effects were often mild to moderate and often resolved within 7 days.

Important: For full safety information and Instructions for Use, please visit www.belotero.com or call Merz Aesthetics Customer Service at 866-862-1211.

Caution: Rx Only