

STRIANT (testosterone buccal system)

A Unique therapeutic option in testosterone replacement

STRIANT (testosterone buccal system) is indicated for testosterone replacement therapy in males with hypogonadism

Consistent from the start without titration

- STRIANT delivers testosterone levels consistently within the physiologic range
- STRIANT consistently maintains DHT levels within normal range

Skin to Skin Transference is Not an Issue

- No Black Box Warnings

Ordering Information

Each STRIANT buccal system contains 30 mg of testosterone and is supplied as follows:

Product	Size	NDC#	WAC
STRIANT	Box of 60	55056-3060-01	\$215.25

Important Safety Information

In the US pivotal trial involving 98 patients, the most frequent adverse events that occurred with an incidence of 1% or greater which were possibly, probably, or definitely related to the use of STRIANT were: gum or mouth irritation (9.2%), bitter taste (4.1%), gum pain (3.1%), gum tenderness (3.1%), headaches (3.1%), gum edema (2.0%), and taste perversion (2.0%). A total of 16 patients reported 19 gum-related adverse events. Of these, 10 patients (10.2%) reported 12 events of mild intensity, 4 patients (4.1%) reported 5 events of moderate intensity, and 2 patients (2.0%) reported 2 events of severe intensity. Four patients (4.1%) discontinued treatment with STRIANT due to gum or mouth-related adverse events including 2 with severe gum irritation, 1 with mouth irritation, and 1 with “bad taste in mouth.” The majority of the gum-related adverse events were transient and resolved within 1 to 14 days. Patients should be advised to regularly inspect the gum region where they apply STRIANT and report any abnormality to their health care professional.

STRIANT is not indicated for women and must not be used in women. Testosterone may cause fetal harm. STRIANT should not be used in patients with known hypersensitivity to any of its ingredients, including testosterone USP that is chemically synthesized from soy.

Androgens are contraindicated in men with carcinoma of the breast or known carcinoma of the prostate. Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required. Gynecomastia frequently develops and occasionally persists in patients being treated with androgens for hypogonadism. The treatment of hypogonadal men with testosterone esters may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung diseases. Geriatric patients treated with androgens may be at an increased risk for the development of prostatic hyperplasia and prostatic carcinoma. In diabetic patients, the metabolic effects of androgens may decrease blood glucose and therefore, insulin requirements.

For Full Prescribing Information Please Visit: http://www.striant.com/Professional/prescribing_info/prescribing_info.asp