

Patient Information

STRIANT® (testosterone buccal system) mucoadhesive

Read the Patient Information that comes with Striant® [STRĪ ant] before you start using it and each time you get a refill. There may be new information. This information does not take the place of information from your healthcare provider about your medical condition or your treatment.

What is Striant®?

Striant® is a hormone medicine that contains testosterone. It is used to treat adult men when their bodies do not make any testosterone or not enough testosterone (hypogonadism). Striant® is a white to off-white tablet-like buccal system that is applied to the upper gum area of the mouth. **Striant® is not to be chewed or swallowed.**

Striant® is a controlled substance (CIII) because it contains testosterone. Therefore, you should keep your Striant® in a secure place. Do not share or sell your Striant®.

Who should not use Striant®?

Do not use Striant® if you:

- have breast cancer (rare in men).
- have prostate cancer.
- are a woman (especially if you are pregnant or breast-feeding). Striant may harm the babies of pregnant and breast-feeding women.
- are allergic to Striant®. The active ingredient in Striant® is testosterone USP. See the end of this leaflet for a list of all ingredients in Striant®.

Tell your doctor if you have or had:

- problems urinating due to an enlarged prostate.
- liver problems.
- kidney problems.
- heart problems.
- lung problems.
- diabetes.
- weight problems (obesity).

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious side effects if taken while you also take Striant®. Some medicines may affect how Striant® works, or Striant® may affect how your other medicines work. Be sure to tell your doctor if you use insulin for diabetes. Your dose of insulin may need to be adjusted if you use Striant®.

How should I use Striant®?

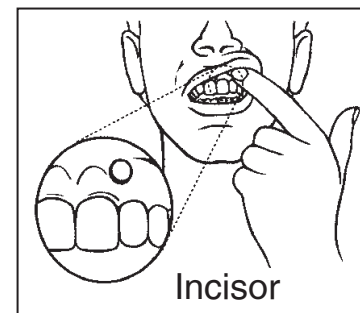
Use Striant® twice a day, once in the morning and once at night (about 12 hours apart). You may find it convenient to apply morning dose after brushing your teeth following breakfast and evening dose following your evening meal.

Striant® should be applied as follows:

- Tear off individual unit then start at the corner tab and peel off paper backing. Push buccal system through foil from the front. You will notice that Striant® is curved on one side and flat on the other side. The flat side has a marking on it (company logo).

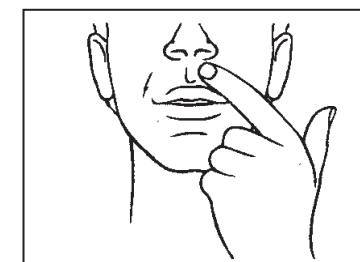


- Before you apply Striant®, locate the area on your upper gum, just above either the left or right incisor (see picture). The incisor is the tooth just to the right or left of your two front teeth.



- Place the flat side of the Striant® system on your fingertip. Gently push the curved side of Striant® against your upper gum in the area shown. Push the Striant® system up as high as it will go on the gum. If you have applied Striant® correctly, the flat side will be facing your cheek.

- Using your finger on the outside of your upper lip, hold the Striant® buccal system in place for 30 seconds (see picture). This will make the buccal system stick to your gum or cheek.



- As the Striant® buccal system absorbs moisture from your mouth, it will begin to soften and will mold to the shape of your gum. You should be aware that Striant® does not dissolve completely, but will remain in place for 12 hours. Striant® is made to stay in place until you remove it.

- Remove Striant® by gently sliding it to the front or back of your mouth to loosen it. Then slide it downwards from your gum to your tooth. This will avoid scratching the gum.

- **With each application, you should rotate Striant® to alternate sides of your mouth.**

- If Striant® does not stick or falls off within the first 8 hours, remove the original system and apply a new one. This counts as replacing the first dose. Apply the next system about 12 hours after the original buccal system was applied.

- If Striant® falls off after 8 hours but before 12 hours, replace the original buccal system. This replacement can serve as the second dose for that day.
- If Striant® sticks to your cheek and not your gum, this is acceptable. Do not replace the buccal system if this should happen.
- Check to see if Striant® is in place following toothbrushing, use of mouthwash and consumption of food or alcoholic/nonalcoholic beverages. If Striant® does not stick or falls off, follow the above mentioned directions to replace with a new system.

What are the possible side effects of testosterone replacement therapy?

Inform your doctor immediately if any of the following symptoms appear while using Striant®.

- **Liver problems.** Tell your doctor if:
 - Your skin or white part of your eyes turns yellow (jaundice).
 - Your urine turns dark.
 - Your bowel movements (stool) turns light in color.
 - You don't feel like eating for several days or longer.
 - You feel sick to your stomach (nausea).
 - You have lower abdominal pain (stomach).
- **Problems urinating.** Tell your doctor if you develop problems urinating while using Striant®. Older patients who use testosterone replacement therapies may have an increased chance of developing prostate enlargement or prostate cancer.
- **Extra fluid in the body (edema).** Edema can be dangerous if you have heart, kidney or liver problems. Tell your doctor if your ankles and legs swell or if you put on weight quickly.
- **Breathing problems, including a sleep problem called "sleep apnea".** Sleep apnea is when you stop breathing for short times while you are sleeping. This happens more in patients who are overweight or who have lung disease. Tell your doctor if you have breathing problems or if you or your partner notice changes in your breathing when you are sleeping.
- **Penile erections** that are painful, that occur too frequently, or that last for too long a duration.
- **Breast enlargement** – which sometimes does not go away.
- **Emotional changes** – such as depression.

Your doctor may do blood tests to check your red blood cells, liver function, cholesterol levels, testosterone levels and prostate (PSA) while you are using Striant®, to see how Striant® is affecting your body.

Striant® may also cause these side effects:

- redness, irritation, swelling and pain at the gum application site.
- gum infection (gingivitis)-gum side effects are usually temporary, and should resolve within several days. However, some gum side effects may last up to two weeks. If you should have gum side effects, they usually

resolve while taking Striant®. Any abnormal finding should be brought to the attention of your physician.

- a change in how food tastes to you, a bitter taste in your mouth, or an unusual taste in your mouth.
- headache.

These are not all the possible side effects of Striant®. For more information, ask your doctor or pharmacist.

You should regularly examine your gums where Striant® is applied. Any abnormal finding should be brought to the attention of your physician.

How should Striant® be stored?

Keep Striant® at a temperature between 68° and 77° F (20-25° C). Protect from heat and moisture. Do not use a damaged blister package. **Keep Striant® and all medicines out of the reach of children.** Discarded Striant® buccal systems should be thrown away in a household trash can in a way that prevents children or pets from accidentally using or taking them.

General information about the safe and effective use of Striant®. Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Striant® for a condition for which it was not prescribed. Do not give Striant® to other people, even if they have the same symptoms you have. It may harm them, and you should be aware that Striant® is a controlled substance.

This leaflet summarizes the most important information about Striant®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Striant® that is written for health professionals.

What are the ingredients of Striant®?

Active Ingredient: Testosterone USP (30 mg in each buccal system)

Inactive Ingredients: anhydrous lactose NF, carbomer 934P, hypromellose USP, magnesium stearate NF, lactose monohydrate NF, polycarbophil USP, colloidal silicon dioxide NF, starch NF, and talc USP.

How is Striant® supplied?

Striant® is supplied in a transparent blister in a white card. Each card contains 10 buccal systems. There are a total of 6 blister cards (60 buccal systems) in each carton.

Rx Only

Manufactured by: Mipharm S.p.A, Milan, Italy

Manufactured for: Columbia Laboratories, Inc., Livingston, NJ 07039

US Patent Numbers: 6,248,358

others pending

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