

FREQUENTLY ASKED QUESTIONS

1. Why is BC Transplant making this change?

In Canada, it's quite common for brand changes to occur. BC Transplant selects the suppliers of anti-rejection medications, such as tacrolimus, for solid organ transplant patients by careful and extensive review processes. This brand conversion from Prograf to Sandoz tacrolimus allows us an opportunity to maximize resources, expand coverage for new treatments, and improve patient access to more medications.

Prograf and Sandoz tacrolimus have identical medications inside the capsules and both brands work the same way in the body.

2. What about patient safety?

Patient safety is our top priority. This brand change has been extensively reviewed and approved by transplant medical experts in BC and is supported by extensive research. A list of clinical studies is available on [our website](#).

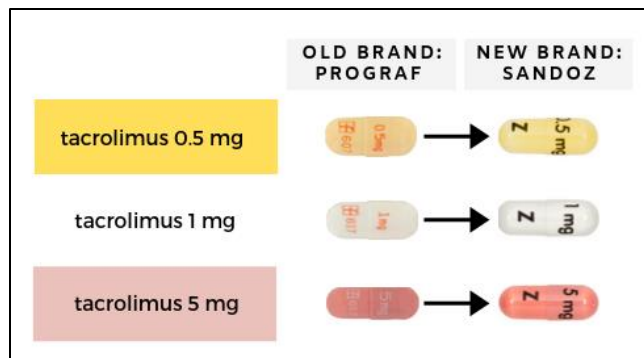
Sandoz tacrolimus is approved by Health Canada and is already in widespread use in other provinces and in the States. Prograf and Sandoz tacrolimus have the identical active medication inside each product.

We do not expect any impact to patient safety; however any new, severe or persistent side effects should be reported to your transplant team as soon as possible.

3. Are there any differences between Prograf and Sandoz tacrolimus?

Although the active ingredient is the same, the inactive ingredients may differ between Prograf and Sandoz tacrolimus. This is important in the rare event that a patient has an allergy or intolerance to one of the inactive ingredients. If you have any signs of an allergic reaction such as rash, shortness of breath, swelling of your mouth or throat, call 911 right away.

Sandoz tacrolimus is slightly different in colour, shape, and markings compared to Prograf.



Please refer to the [Patient Information Sheet](#) for more details.

4. How will Sandoz tacrolimus be prescribed?

All new transplant patients transplanted starting November 4, 2019 will be prescribed Sandoz tacrolimus.

If you are a transplant patient currently taking Prograf, you will receive a letter informing you of the brand change. Your transplant team will also provide information sheets and education in the clinic or over the phone, depending on your next clinic date. You will be advised to use up your home supply of Prograf before starting on Sandoz tacrolimus.

This change will start at different times, depending on where your transplant clinic is located.

- Prince George, Kelowna, Kamloops, Penticton and Trail post-transplant clinics: to start on **November 18, 2019**.
- Vancouver General Hospital (Diamond Centre), St. Paul's Hospital, BC Children's Hospital, Fraser Health (Surrey), Victoria, and Nanaimo post-transplant clinics: to start on **January 6, 2020**.

You will receive a lab requisition for tacrolimus levels check. You must get this test done five to seven days after you start Sandoz tacrolimus.

If necessary, your clinic will follow up with you based on your tacrolimus levels results. You may be asked to get an additional tacrolimus levels check, or adjust your dose and monitor for side effects.

5. What patient supports and resources are available?

BC Transplant has developed information handouts to help you and your family understand how and why this brand change is occurring. Your transplant team will review this information with you at your next clinic visit or by phone. Please visit [our website](#) for more information. If you have further questions or concerns, please contact your transplant team.

6. Are there potential new side effects?

The active medication in Sandoz tacrolimus is identical to Prograf. Therefore, we do not anticipate you will have any different side effects than those from Prograf. As with any change in medication, if you experience any new and persistent symptoms - such as headaches, tremors or diarrhea - please contact your transplant team as soon as possible.

If you have any signs of an allergic reaction - a rash, swollen lips, neck or throat, or difficulty breathing - contact your transplant clinic or call emergency services (911) right away.

7. What are the reported rates of side effects for Sandoz tacrolimus? How does this compare to Prograf?

The most common side effects of Sandoz tacrolimus are the same as Prograf. These may include diarrhea, nausea, headache, tremors, tiredness or fatigue, loss of appetite, stomach pain etc.

It is not expected that you will experience any new side effects, however please contact your transplant team if you are having any unexpected symptoms especially if they are severe and continue to be a problem for many days.

8. Is there a possibility the brand change will trigger rejection?

Sandoz tacrolimus and Prograf have been extensively studied to have similar benefits to prevent rejection. The probability of rejection on Sandoz tacrolimus is the same as that on Prograf, which depends on your body's immune function and stability of the graft.

9. What if I forget to switch? Or if I stop Prograf and don't start Sandoz tacrolimus?

It is very important that you continue to take your anti-rejection medications. Your transplant clinic team will be closely monitoring your conversion date for follow up tacrolimus levels check.

10. Why is it so important not to switch between brands, especially if you say both are equally effective and are supposed to act the same?

Certain medications such as tacrolimus need careful dosing to make sure it works best for you and your body. This is the reason why your transplant clinic will check your tacrolimus levels after you change to Sandoz tacrolimus. Although Sandoz tacrolimus and Prograf tacrolimus have identical effects, it is important not to switch between brands on your own.

11. What do I do with any leftover Prograf tacrolimus?

You will be asked to use up your Prograf before your conversion date. However, if you have any leftover Prograf at home after switching to Sandoz, please return the medication to your pharmacy for proper disposal.

If you have any additional questions, please contact your transplant clinic.