

PATIENT INFORMATION BOOKLET

TARO-Fingolimod



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Taro-Fingolimod is a therapy used for adult patients with relapsing-remitting multiple sclerosis (RRMS). It is used to decrease the frequency and severity of attacks and delay progression of RRMS. It is to be taken alone and not combined with other medications that change the immune system to reduce relapse rates of MS. Taro-Fingolimod is generally recommended for people who did not tolerate, or have responded poorly to, other medications used for RRMS. It is not recommended for people with heart disease or for those who are taking medications that can decrease the heart rate.

Taro-Fingolimod is contraindicated in women who are pregnant or of childbearing potential not using effective contraception. Pregnancy must be excluded before start of treatment as fingolimod may cause fetal harm.

Effectiveness

Taro-Fingolimod is not a cure for MS, but it helps to:

- reduce the relapse rate of MS by about 50%
- decrease shrinking of brain tissue and swelling in the brain
- slow progression of the disease and the disability it causes

Adverse Effects

The most serious side effects that were reported in animal and human studies were birth defects, an increase in risk of infections (most commonly influenza [the 'flu'] or other respiratory infections), macular edema (swelling of the macular area of the retina, at the back of the eye), a slowed heartbeat, and heart block (change in heart rhythm). The most frequent side effects that occurred in studies with this medication were headache, influenza, diarrhea, back pain, and cough. Liver problems were the most common reason to discontinue therapy in studies. Seizures have occurred in some people taking fingolimod.

Tell your doctor if you have already had a reaction to this medicine or if you have allergies to non-drug ingredients (such as fillers or dyes) that are commonly used in capsules.

Your doctor will ensure that you follow the monitoring plan below to prevent or promptly detect these and other side effects that may affect your health.

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What to Expect As You Start Therapy with Taro-Fingolimod ... Your Checklist

Before starting the medication you will need:

- a complete blood count (CBC) blood test to check your level of lymphocytes (a type of white blood cell)
- a test for immunity to varicella zoster virus (VZV, chickenpox), unless you have documented exposure to the vaccine or the virus
 - If no immunity, you will need a course of VZV vaccine before starting the medication and will need to wait one month for immunity to develop before starting this treatment.
- a blood test to determine your levels of liver enzymes, as Taro-Fingolimod can affect liver function
- If you have diabetes or have had uveitis, you will need an eye exam before starting therapy as well as ongoing monitoring, as you are at greater risk of developing macular edema.
- If you are a woman who is able to become pregnant, your doctor may ask you to have a pregnancy test to ensure you are not pregnant, as Taro-Fingolimod can cause birth defects.
- You will also need to discuss effective birth control options with your doctor or other healthcare professional.
 - You should avoid becoming pregnant while taking Taro-Fingolimod or in the two months after you stop taking it because of the risk of harming your unborn child.
 - If you do become pregnant while taking Taro-Fingolimod, tell your doctor right away. You and your doctor will decide what is best for you and your baby.
 - If you become pregnant while taking Taro-Fingolimod, you can call the Taro-fingolimod Pregnancy Registry at 1.866.877.5180.

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When You Start Therapy:

You will be supervised in hospital, a clinic, or your doctor's office for at least six hours after taking the first dose to ensure your heart rate does not drop too low.

- An ECG (heart monitoring test) will be performed before the first dose and again six hours later to make sure no serious changes have occurred in the heart.
 - Your doctor may use a continuous ECG monitor as an alternate option.
- Your blood pressure and heart rate will be checked before the first dose and then every hour for at least six hours to monitor heart-related side effects.

If your heart rate slows more than desired or has not started to rebound by six hours after you take the first dose, you will need to stay at the hospital longer and possibly overnight for observation. You may also be monitored as you take your second dose.

Note: You will not be able to drive on the day you take your first dose due to possible dizziness caused by a slowed heart rate.

NOTE: Monitoring that was done for the first dose will need to be repeated if your therapy is interrupted:

- for one day in the first two weeks
- for seven or more days in weeks 3 and 4
- for 14 or more days at any time

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Ongoing Monitoring During Treatment and for Two Months After Stopping Taro-Fingolimod:

- Blood tests for liver function will be repeated every three months for the first year and periodically after the first year (usually twice a year).
 - Let your doctor know immediately if you have any signs of liver disease: unexplained vomiting, abdominal pain, fatigue, loss of appetite, jaundice (yellowing of eyes and skin), and/or dark urine.
- Note: Liver problems, if they occur, generally clear up when treatment is stopped.**
- An eye exam is recommended after three to four months of therapy to ensure no macular edema (swelling at the back of the eye) has developed.
 - Report any visual changes promptly to your doctor.
- **See your doctor immediately if you have any signs of infection (which will vary, depending on the type of infection):**
 - fever, fatigue, cough, nausea, diarrhea, muscle aches, rash
- Report any new or increased difficulty in breathing to your doctor as soon as possible, as Taro-Fingolimod can cause increased breathing difficulty in some people.
- Monitor your skin for any unusual lesions (patches, shiny pearly “nodules” or small bumps), as an increased risk of certain skin cancers such as basal cell carcinoma has been reported. Report any unusual lesions that do not heal normally or have changed in appearance promptly to your doctor.
- Tell any other doctor you see that you are taking Taro-Fingolimod and need to avoid other medications that slow your heart rate.
 - Tell your doctor immediately if you have symptoms of a slow heart rate, such as heart palpitations or dizziness.

NOTE: It may take up to two months for all medication to be removed from your body. Stopping Taro-Fingolimod may cause the disease activity to return. Continue to report any concerns to your doctor and, if you are a woman, avoid pregnancy during this time.

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