ALRAZI® الرازي
PHARMA INDUSTRIES للصناعات الدوائية

Figoya (fingolimod)

Physician's Checklist

This Physician Checklist is essential to ensure the safe and effective use of Figoya (fingolimod) and for the appropriate management of important safety risks.

Please be advised to carefully read before prescribing, dispensing, and administering the product.

SFDA Website

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Considerations in fingolimod Patient Selection

- Fingolimod is indicated as single disease modifying therapy for highly active relapsing-remitting multiple sclerosis (RRMS) in adult patients and pediatric patients aged 10 years and older.
- While many patients are suitable for treatment, the following section highlights patients in whom fingolimod is contraindicated or not recommended.
- Fingolimod causes transient heart rate reduction and may cause atrioventricular (AV) conduction delays following initiation of treatment. All patients should be monitored for a minimum of 6 hours on treatment initiation. Below is a brief overview of monitoring requirements.
- Fingolimod is generally recommended in MS patients who have had an inadequate response to, or are unable to tolerate, one or more therapies for multiple sclerosis.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Contraindications

Fingolimod is contraindicated in patients with:

- Hypersensitivity to fingolimod hydrochloride or to any of the excipients in the formulation of fingolimod or component of the container.
- Increased risk for opportunistic infections, including those who are immunocompromised due to treatment (e.g. antineoplastic, immunosuppressive or immunomodulating therapies, total lymphoid irradiation or bone marrow transplantation) or disease (e.g. immunodeficiency syndrome).
- Severe active infections, including active chronic bacterial, fungal or viral infections (e.g. hepatitis, turberculosis).
- Known active malignancies (except patients with basal cell carcinoma (BCC)).
- Severe hepatic impairment (Child-Pugh class C).
- In the previous 6 months, myocardial infarction (MI), unstable angina pectoris, stroke/transient ischaemic attack (TIA), decompensated heart failure (requiring inpatient treatment), or New York Heart Association (NYHA) class III/IV heart failure.
- Patients with severe cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs.
- Patients with second-degree Mobitz type II AV block or third-degree AV block,Cor sick-sinus syndrome (if they do not wear a pacemaker).
- Patients with a baseline QTc interval of ≥ 500 msec.
- Pregnant women and women of childbearing potential not using effective contraception.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Not Recommended

Consider fingolimod only after performing risk/benefit analysis and consulting a cardiologist

Consult cardiologist regarding appropriate first-dose monitoring

Sino-atrial heart block, history of symptomatic bradycardia or recurrent syncope, significant QTc prolongation > 470 msec (females) or > 450 msec (males), or risk factors for QT prolongation, history of cardiac arrest, uncontrolled hypertension or severe sleep apnoea	At least overnight extended monitoring is recommended

Consult cardiologist regarding possibility of switching to non-heart-rate-lowering drugs

Taking beta-blockers, heart-rate-lowering calcium channel blockers § , or other substances that are known to lower the heart rate ||	If change in medication is not possible, extend monitoring to at least overnight

§ Such as verapamil or diltiazem
|| Includes digoxin, cholinesterase inhibitors, or pilocarpine.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Treatment Initiation Algorithm

- All patients will need to be monitored for at least 6 hours during treatment initiation, as described in the algorithm below.
- In addition, for patients in whom fingolimod is not recommended, advice should be sought from a cardiologist regarding appropriate monitoring; at least overnight monitoring is recommended for this group.
- This procedure should also be followed in pediatric patients when the dosage is increased from 0.25 mg to 0.5 mg once daily.

Monitor for a minimum of 6 hours

- ☐ Perform ECG and BP measurement
- ☐ Monitor for a minimum of 6 hours for signs and symptoms of bradycardia, with hourly pulse and BP checks. If patient is symptomatic, continue monitoring until resolution
  - Continuous (real-time) ECG is recommended throughout the 6-hour period
- ☐ Perform ECG at 6 hours

☐ Did the patient require pharmacologic intervention at any time during the monitoring period?

Yes ▶ Monitor overnight in a medical facility. The first dose monitoring should be repeated after the second dose of fingolimod

No

☐ Did third-degree AV block occur at any time during the monitoring period?

Yes ▶ Extend monitoring at least overnight, until the findings have resolved

No

At the end of the monitoring period, have any of the following criteria been met?

- ☐ HR < 45 bpm (for Adult)
- ☐ HR < 55 bpm in pediatric patients aged ≥12 years old, or <60 bpm in pediatric patients aged 10 to <12 years of age.
- ☐ ECG shows new-onset second-degree or higher AV block or QTc interval ≥ 500 msec

Yes ▶ Extend monitoring at least overnight, until the findings have resolved

No

☐ At the end of the monitoring period, is the HR the lowest since the first dose was administered?

Yes ▶ Extend monitoring by at least 2 hours and until heart rate increases

No

☐ First-dose monitoring is complete

Yes ▶ The above first-dose monitoring procedure should also be followed at reinitiation of treatment if fingolimod therapy is discontinued for

- One day or longer within the first 2 weeks of treatment.
- More than 7 days during weeks 3 and 4 of treatment.
- More than 2 weeks after the first month of treatment.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Physician's Checklist

Physician Checklist–Recommended Steps to Managing Patients on Fingolimod

The checklist and schematic that follow are intended to assist in the management of patients on fingolimod. Key steps and considerations while starting, continuing, or discontinuing treatment are provided.

Prior to initiating treatment
☐ Ensure patients are not concomitantly taking Class Ia or Class III antiarrhythmic medicines.
☐ Conduct baseline electrocardiogram (ECG) and blood pressure measurement.
☐ Treatment with fingolimod should not be used in the following patients, unless anticipated benefits outweigh the potential risks. • Those with sino-atrial block, history of symptomatic bradycardia, significant QT-interval prolongation, or in patients with relevant risk factors for QT prolongation (e.g., hypokalemia, hypomagnesemia or congenital QT prolongation), history of cardiac arrest, uncontrolled hypertension or severe untreated sleep apnoea ☐ Seek advice from a cardiologist regarding the most appropriate monitoring at treatment initiation; at least overnight extended monitoring is recommended • Those receiving concurrent therapy with beta-blockers, heart-rate-lowering calcium channel blockers (such as verapamil or diltiazem), or other substances which may decrease heart rate (e.g., digoxin, cholinesterase inhibitors, orpilocarpine) ☐ Seek advice from a cardiologist regarding a switch to non-heart-rate-lowering medicinal products prior to initiation of treatment ☐ If heart-rate-lowering medication cannot be stopped, seek advice from a cardiologist regarding the most appropriate monitoring at treatment initiation; at least overnight extended monitoring is recommended

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Physician's Checklist

Prior to initiating treatment	
☐	Avoid co-administration of anti-neoplastic, immunosuppressive or immunomodulatory therapies due to the risk of additive immune system effects. For the same reason, a decision to use prolonged concomitant treatment with corticosteroids should be taken after careful consideration.
☐	Obtain recent (within 6 months) transaminase, and bilirubin levels.
☐	Obtain recent (within 6 months or after discontinuation of prior therapy) peripheral lymphocyte count (complete blood count (CBC)). Treatment should not be initiated when lymphocyte counts are consistently below normal range.
☐	Fingolimod is teratogenic. Inform women of child-bearing potential, including adolescent females, their parents/caregivers that it is contraindicated in women of childbearing potential not using effective contraception and in pregnant women.
☐	Confirm a negative pregnancy test result in women of childbearing potential, including adolescent females, prior to starting treatment, and it must be repeated at suitable intervals during treatment.
☐	Counsel women of child-bearing potential including adolescent females, their parents (or legal representatives), and caregivers about the serious risks of Fingolimod to the fetus, facilitated by the Patient Reminder Card. Counsel also on the need for effective contraception in women of childbearing age up to at least 2 months after completion or discontinuation of treatment, due to teratogenic risk to fetus.
☐	Delay initiation of treatment in patients with severe active infection until resolved.
☐	Human papilloma virus (HPV) infection, including papilloma, dysplasia, warts and HPV-related cancer, has been reported in the post-marketing setting. Cancer screening (including a Pap test), and vaccination for HPV-related cancer is recommended for patients as per standard of care.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Physician's Checklist

☐	Check varicella zoster virus (VZV) antibody status in patients without a healthcare-professional-confirmed history of chickenpox or documentation of a full course of varicella vaccination. If negative, a full course of vaccination with varicella vaccine is recommended and treatment initiation should be delayed for 1 month to allow full effect of vaccination to occur
☐	Conduct an ophthalmologic evaluation in patients with history of uveitis or diabetes mellitus
☐	Conduct a dermatologic examination. The patient should be referred to a dermatologist if suspicious lesions, potentially indicative of basal cell carcinoma, or other cutaneous neoplasms (squamous cell carcinoma, Kaposi's sarcoma and Merkel cell carcinoma), are detected
☐	Provide patients with a Patient Reminder Card

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Physician's Checklist

During treatment
☐ Conduct a full ophthalmologic evaluation in all patients at 3 to 4 months after starting treatment and in any patient complaining of visual disturbances ● Conduct periodic ophthalmologic evaluations in patients with history of uveitis or diabetes mellitus ● Counsel patients to report any visual disturbance during treatment ● Evaluate the fundus, including the macula, and discontinue treatment if macular oedema is confirmed
☐ Counsel patients to report signs and symptoms of infection ● Prompt antimicrobial treatment should be initiated if indicated ● Perform prompt diagnostic evaluation in patients with symptoms and signs consistent with cryptococcal meningitis, and initiate appropriate treatment if diagnosed (cryptococcal meningitis, sometimes fatal, has occurred after 2-3 years of treatment, although an exact relationship with the duration of treatment is unknown) ● Be vigilant for clinical symptoms or MRI findings that may be suggestive of progressive multifocal leukoencephalopathy (PML). If PML is suspected, treatment with fingolimod should be suspended until PML has been excluded (cases of PML have occurred 2-3 years of treatment, although an exact relationship with the duration of treatment is unknown) ● If a patient develops a serious infection, treatment should be suspended ● Discontinue treatment in disseminated herpetic infections.
☐ Check full blood count periodically during treatment, at month 3 and at least yearly thereafter, and interrupt treatment if lymphocyte count is confirmed as <0.2x109/L. The approved dosing of 0.5 mg once daily when restarting fingolimod should be administered. Other dosing regimens have not been approved.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Physician's Checklist

☐ Check liver transaminases and bilirubin levels prior to initiating treatment if no recent (i.e. within the last 6 months) results is available, and at months 9 ,6 ,3 ,1, and 12 and at regular intervals thereafter on therapy, until 2 months after fingolimod discontinuation, or at any time there are signs or symptoms of hepatic dysfunction

- Institute more frequent monitoring, including ALP, if liver transaminases rise above 3 times the reference range
- Interrupt treatment if liver injury is confirmed (ALT above 5 times the reference range or ALT above 3 times the reference range with serum total bilirubin above 2 times the reference range)

☐ During treatment and for up to 2 months after discontinuation

- Vaccinations may be less effective
- Live attenuated vaccines may carry a risk of infection and should be avoided

While on treatment, women must not become pregnant. Counsel patient to advise physician immediately if she becomes pregnant. Discontinue treatment if a woman becomes pregnant while on treatment with Fingolimod.
Fingolimod must be stopped 2 months before planning a pregnancy. When stopping Fingolimod therapy due to pregnancy or for planning a pregnancy, the possible return of disease activity should be considered. Counsel the patient regarding the risk of harmful effects to the foetus associated with Fingolimod treatment and ultrasonography examinations should be performed.

- Advise women of childbearing potential (including adolescents and their parents/legal representatives/caregiver) that effective contraception must be used during treatment and for at least 2 months after treatment discontinuation.
- Pregnancy tests must be repeated at suitable intervals
- Ensure women of childbearing potential (including adolescents and their parents/legal representatives/caregivers) receive regular counselling facilitated by the Patient Reminder Card
- To help determine the effects of fingolimod exposure in pregnant women with MS, physicians are encouraged to report pregnant patients who may have been exposed to fingolimod at any time during pregnancy (from 8 weeks prior to last menstrual period onward) to:
  National Pharmacovigilance Centre (NPC) at the Unified Contact Center: 19999, or Email: npc.drug@sfda.gov.sa or online: https://ade.sfda.gov.sa.
  or by contacting ALRAZI Pharma Company via PV@alrazi-pharma.com, phone: +281919 13 966.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Physician's Checklist

☐	Vigilance for basal cell carcinoma and other cutaneous neoplasms is recommended, with skin examination prior to treatment initiation and then yearly taking into consideration clinical judgment and referral to a dermatologist if suspicious lesions, potentially indicative of basal cell carcinoma or other cutaneous neoplasms, are detected. Caution patients against exposure to sunlight without protection. These patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.
☐	Fingolimod has an immunosuppressive eect that predisposes patients to an infection risk, including opportunistic infections that can be fatal, and increases the risk of developing lymphomas (including mycosis fungoids), and other malignancies (particularly those of the skin). Physicians should carefully monitor patients during treatment, especially those with concurrent conditions or known factors such as previous immunosuppressive therapy. Surveillance should include vigilance for both skin malignancies and mycosis fungoides. If this risk is suspected, discontinuation of treatment should benconsidered by the physician on a case-by-case basis
☐	Cases of seizure, including status epilepticus, have been reported. Vigilance for seizures, especially in those patients with underlying conditions or with a pre-existing history or family history of epilepsy, is recommended.
☐	Monitor pediatric patients for signs and symptoms of depression and anxiety
☐	Reassess annually the benefit of fingolimod treatment versus the potential risks in each patient, especially in pediatric patients.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Physician's Checklist

After treatment discontinuation	
☐	Repeat first-dose monitoring as for treatment initiation when treatment is interrupted for: ● One day or more during the first 2 weeks of treatment ● More than 7 days during weeks 3 and 4 of treatment ● More than 2 weeks after 1 month of treatment
☐	Counsel patients to report signs and symptoms of infection for up to 2 months after discontinuation
☐	Counsel patients that effective contraception is needed for 2 months after discontinuation
☐	Advise women who stop treatment with Fingolimod because they are planning a pregnancy that their disease activity may return
☐	Vigilance for the possibility of severe exacerbation of disease following discontinuation of treatment is recommended

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0

Figoya (fingolimod)

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Al Razi Pharmaceutical Company
Pharmacovigilance Department
Tel: 013 828 1919
Phone: 966554833113
website: www.alrazi-pharma.com
E-mail: PV@alrazi-pharma.com

The National Pharmacovigilance Center (NPC)
at Saudi Food and Drug Authority SFDA
E-mail: npc.drug@sfda.gov.sa
Online: https://ade.sfda.gov.sa
Toll free phone: 19999

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA)

Date: 01.2026, Version 1.0