

Patient Guide

Patients:

Your healthcare provider will go over this patient guide with you. It is important to ask any questions you may have. Keep this guide for important safety information about the risk of liver injury (serious liver problems) and the possibility of harm to an unborn baby with this medicine in adults with thalassemia.

Healthcare Providers:

Review this guide with your patient and provide your patient with a copy to take home.

WHAT IS PYRUKYND?

PYRUKYND contains the active substance mitapivat and is under the pharmacotherapeutic group of 'other hematological agents'.

PYRUKYND is used to treat adults with an inherited condition called thalassemia, regardless of their transfusion needs. Patients with thalassemia have red blood cells that break down too fast, a process known as hemolytic anemia.

PYRUKYND helps an enzyme in red blood cells, called pyruvate kinase, work better to increase the energy in your red blood cells and stops them from being broken down too fast.

WHAT ARE THE SERIOUS RISKS OF PYRUKYND?

Liver Injury (serious liver problems)

This medicine can cause liver injury (serious liver problems) in patients with thalassemia.

Liver injury has happened during the first 6 months of treatment with this medicine.

- Your healthcare provider will use blood tests to check your liver tests before you start treatment and monthly for the first 6 months of treatment.
- If your liver tests are higher than what they used to be before starting the medication, your doctor may temporarily or permanently stop treatment. Your doctor will monitor you for any signs of serious damage to your liver.

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You should stop taking this medicine and you or your family member should contact your healthcare provider right away if you have any of the following symptoms:

Yellowing of the skin or whites of your eyes (jaundice)



Dark colored urine



Pain in the upper right part of your belly



Nausea



Vomiting



Loss of appetite



Harm to an Unborn Baby

There is little information about the use of this medicine in pregnant women. Studies in animals have shown harm to an unborn baby.

If you are pregnant, think you may be pregnant, or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should avoid becoming pregnant during treatment.

- This is because it may cause harm to your unborn baby.
- Talk to your doctor straight away if you become pregnant while taking this medication.

If you could become pregnant, you must use reliable contraception while taking this medicine.

- Some birth control medicines containing hormones (such as pills) may not work as well as expected while taking this medicine, meaning you might be at risk of becoming pregnant.
- If using hormones for birth control, also use a barrier method (such as a condom), or use an alternative non-hormonal method while taking this medicine and for 1 month after the last dose.
- Talk to your doctor, pharmacist or nurse about contraception methods that may be right for you while you are using this medicine.

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Please refer to the Patient Information Leaflet for further information.

IF YOU HAVE ANY QUESTIONS ABOUT YOUR HEALTH OR MEDICINES, TALK TO YOUR HEALTHCARE PROVIDER.

REPORTING EVENTS OF LIVER INJURY AND PREGNANCY

Adverse events (symptoms) of liver injury and events of pregnancy should be reported to both the Saudi Food and Drug Authority (SFDA) and Agios Pharmaceuticals, Inc. using the contact information below:

Kingdom of Saudia Arabia

National Pharmacovigilance Center (NPC)-
Saudi Food and Drug Authority
SFDA Call center: 19999
Email: npc.drug@sfd.gov.sa
Website: <http://ade.sfda.gov.sa/>



Agios Pharmaceuticals, Inc.

Email: safety_operations@agios.com
KSA QPPV: Asayel Ali Mousa
Deputy QPPV: Saba Bin Huwaimel

QPPV-Qualifies Person for Pharmacovigilance

To request additional copies of this guide, contact safety@balsam-cr.com.