pyrukynd®
(mitapivat) tablets
100 mg

RISKS ASSOCIATED WITH USE OF PYRUKYND (MITAPIVAT)

Healthcare Professional Guide

This guide aims to ensure safe and effective use of PYRUKYND by minimizing the risks of hepatocellular injury and embryo-fetal toxicity. It is advised to read carefully before prescribing the product.

INDICATION

PYRUKYND 100 mg film–coated tablets are indicated for the treatment of adult patients with non–transfusion–dependent and transfusion–dependent alpha– or beta–thalassemia.

RISK OF HEPATOCELLULAR INJURY

Liver injury has been observed within the first 6 months of treatment in patients with thalassemia with peak elevations of alanine aminotransferase (ALT) ≥5×upper limit of normal (ULN) with or without jaundice. All patients discontinued treatments with PYRUKYND, and these events improved upon treatment discontinuation.

To mitigate the risk of hepatocellular injury, prescribers should adhere to the following:

- Counseling patients about the risk of hepatocellular injury, including signs and symptoms, and the need for monthly monitoring for the first 6 months of treatment
- Providing the Risks Associated with Use of PYRUKYND (mitapivat): Patient Guide before starting treatment and reinforcing key messages to the patient at each monthly visit from Month 1 to Month 6
- Obtaining liver tests prior to treatment to establish a baseline and monthly thereafter for 6 months and as clinically indicated
- Conducting a comprehensive work-up for acute changes in liver tests to rule out drug-induced liver injury (DILI)
- Interrupting treatment as described in the labeling if clinically significant increases in liver tests are observed or **ALT is >5×ULN**
- Discontinuing treatment if hepatocellular injury due to the product is suspected

Refer to the Summary of Product Characteristics, Section 4.4 Special warnings and precautions for use and Section 4.8 Undesirable effects for additional information on the risk.

EMBRYO-FETAL TOXICITY AND HORMONAL CONTRACEPTION

There is no or limited amount of data from the use of PYRUKYND in pregnant women. Studies in animals have shown reproductive toxicity.

Refer to the Summary of Product Characteristics, Section 5.3 Preclinical safety data for detailed descriptions of the findings from animal studies.

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EMBRYO-FETAL TOXICITY AND HORMONAL CONTRACEPTION (continued)

Women of childbearing potential should avoid becoming pregnant while receiving PYRUKYND and therefore should use contraception during treatment and for at least 28 days after the last dose.

- PYRUKYND may decrease the systemic concentrations of hormonal contraceptives that are sensitive to substrates of CYP3A4 (eg, ethinyl estradiol)
- For patients using hormonal contraceptives, concomitant use of a barrier method of contraception or an alternative non-hormonal contraceptive method is recommended

Refer to the Summary of Product Characteristics, Section 4.5 Interaction with other medicinal products and other forms of interaction and Section 4.6 Fertility, pregnancy, and lactation for additional information.

REPORTING EVENTS OF HEPATOCELLULAR INJURY, PREGNANCY, OR EMBRYO-FETAL TOXICITY

Adverse events of hepatocellular injury, events of pregnancy or embryo-fetal toxicity 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@sfda.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.

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