PALomino

For more information about the PALomino study and how to enroll a patient, please call 833-672-2203 or visit palominostudy.com.

BIOMARIN

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Consider the PALomino Pregnancy Observational Safety Study for your patients with phenylketonuria (PKU) treated with Palynziq® (pegvaliase)

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

PALomino is a global, multicenter observational safety study sponsored by BioMarin Pharmaceutical Inc. to assess maternal, fetal, and infant outcomes in women exposed to Palynziq® (pegvaliase) during pregnancy and breastfeeding.

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Purpose of the PALomino Pregnancy Observational Safety Study

Limited data from case reports of Palynziq® use in pregnant women are insufficient to determine a drug-associated risk of adverse developmental outcomes. The purpose of this study is to increase knowledge about the outcomes of pregnant women with PKU and their offspring exposed to Palynziq® during pregnancy, including breastfeeding outcomes (low milk supply) and infant outcomes (failure to thrive and developmental concerns) through the first year of life.

High maternal blood phenylalanine (Phe) levels are independently associated with adverse pregnancy outcomes including increased risk of miscarriage and congenital malformations (CMs). Conversely, very low maternal Phe concentrations during the second and third trimesters are a risk factor for fetal growth restriction. Monitoring and evaluating women with PKU treated with Palynziq® can help in assessing the impact of exposure on pregnancy and breastfeeding.

Study eligibility criteria

The PALomino Pregnancy Observational Safety Study is enrolling women who meet the following criteria:

- Confirmation of current pregnancy
- Diagnosis with PKU per local standard of care
- Documentation of Palynziq® treatment at any point during the pregnancy, including 2 weeks prior to the date of first day of last menstrual period. Continuous Palynziq® treatment throughout the pregnancy is not required
- Pregnancy outcome (i.e., pregnancy loss or live birth) is not known at the time of enrollment (patients who have undergone prenatal ultrasound/testing may enroll)
- Agree to allow the study Investigator to contact their Health Care Practitioners (HCPs) (e.g., PKU-treating physician, OB, nurse, midwife) and infant's HCP (e.g., pediatrician, neonatologist) for medical information

Study data collection

Women may be enrolled in the study at any time during the pregnancy. If your patient is taking (or has taken) Palynziq® anytime during her pregnancy and consents to participate, you will be contacted to provide essential information such as medical history, PKU disease status, blood Phe levels, diet, medications (including Palynziq® exposure), pregnancy status, and maternal/fetal safety events. You and your patient's obstetrician will be contacted to provide similar information midway through the second trimester and then at the outcome of the pregnancy. If your patient is taking Palynziq® and breastfeeding, prescription and dosing information will also be collected for up to 12 months after the infant is born. The infant's pediatrician will be contacted to provide information about infant characteristics, including any congenital malformations or other safety events at approximately 4 and 12 months after birth.

A list of all reportable safety events being collected in the study will be provided to you and is also available at palominostudy.com. It is essential that all safety events are reported to the study staff within 1 business day of your awareness of the event.

Your support in providing requested information is important for the study to be able to assess the impact of Palynziq® on pregnancy outcomes.