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Pharma Major Lupin Limited and its US subsidiary, Lupin Pharmaceuticals, Inc. (collectively Lupin) have announced the re-introduction of Methergine (methylergonovine maleate) Oral Tablets 0.2mg for the prevention and management of postpartum hemorrhage (PPH).

Methergine is said to be the only FDA-approved oral uterotonic and is a preferred oral agent in the management of PPH , according to guidelines issued by the American Congress of Obstetricians and Gynecologists (ACOG) . More than half of all maternal deaths occur within 24 hours of birth, most commonly from excessive bleeding , and rates of maternal mortality continue to rise in the US where PPH is a leading cause of pregnancy complications .

"The re-introduction of Methergine is a proud moment for Lupin, but also an important moment for expectant mothers across the country to feel confident in care options," said Mr Paul McGarty, president, Lupin Pharmaceuticals. "With Methergine, Lupin is making a significant investment to help improve the management of PPH, providing professional medical education, leveraging its specialized sales force to drive better awareness and access to care, and ensuring a more stable supply of this essential medicine."

"Postpartum hemorrhage (PPH) is one of the most preventable causes of maternal mortality and it should be better managed in pursuit of improved patient care," said David B. Schwartz, MD, FACOG, independent OBGYN and ACOG fellow. "I commend Lupin for spotlighting this public health issue and making an investment in treatment, education and awareness of PPH."

A semi-synthetic ergot alkaloid, Methergine is indicated for routine management of uterine atony, hemorrhage and subinvolution of the uterus following delivery of the placenta, and for control of uterine hemorrhage in the second stage of labor following delivery of the anterior shoulder.

Methergine provides specific and rapid (onset of action under 10 minutes) uterotonic action on the smooth muscle of the uterus to increase contractions, resulting in restricting blood loss.

The Methergine dosing schedule is one tablet (0.2 mg) three or four times daily in the puerperium for a maximum of one week. The most common adverse event is hypertension associated in several cases with seizure and/or headache. Methylergonovine maleate is available as an intramuscular injection or as an oral tablet; Lupin acquired oral methylergonovine maleate earlier this year.

Postpartum hemorrhage (PPH) is often defined as blood loss in excess of 500 mL after vaginal delivery or 1000 mL after cesarean delivery. It is generally classified as primary - occurring within the first 24 hours of delivery - or secondary, up to 6-12 weeks postpartum.