INTERNATIONAL ABBREVIATED PRESCRIBING INFORMATION: ANGUSTA® 25 microgram tablet (misoprostol)

Presentation: White uncoated tablet. Each tablet contains 25 mcg misoprostol.

Indications: For the induction of labour.

Dosage and Administration: Adults: 25 mcg orally every 2 hours or 50 mcg orally every 4 hours according to hospital practice. Maximum dose is 200 mcg in 24 hours.

Children: The safety and efficacy of ANGUSTA® in pregnant women under 18 years old has not been established. No data are available.

Patients with hepatic or renal impairment: A lower dose and/or prolonged dosing intervals should be considered in pregnant women with renal or hepatic impairment.

Contraindications: Known hypersensitivity to the active substance or to any of the excipients; when labour has started; when there is suspicion or evidence of foetal compromise or foetal malpresentation contraindicating vaginal delivery; when oxytocic drugs and/or other labour induction agents are being given; when there is suspicion or evidence of uterine scar or abnormality; when there is placenta praevia or unexplained vaginal bleeding after 24 weeks gestation with this pregnancy; in patients with kidney failure.

Warnings and Precautions: only to be administered by trained obstetric personnel in a hospital setting where facilities for continuous foetal and uterine monitoring is available and the cervix should be assessed carefully before product use; can cause excessive uterine stimulation; if uterine contractions are prolonged or excessive, or there is a clinical concern for mother or baby, the tablets should not be administered; in women with pre-eclampsia, evidence or suspicion of foetal compromise should be ruled out; chorioamnionitis may necessitate fast delivery; no/limited clinical data in women whose membranes have been ruptured for more than 48 hours prior to administration; there may be synergistic additive effects of ANGUSTA and oxytocin, so concomitant use is contraindicated; no/limited data in multiple pregnancies, grand multiparity, use before week 37 of gestation and women with Bishop score >6; use only when induction of labour is clinically indicated; increased risk of post-partum disseminated intravascular coagulation has been described in patients whose labour has been induced by any physiological or pharmacological method.

Interactions: No interaction studies have been performed. Concurrent use of oxytocic drugs or other labour induction agents is contraindated due to potential of increased uterotonic effects.

Fertility, Pregnancy and Lactation: Studies of fertility and embryo development in rats showed a possible impact on implantation and resorption, however this has no relevance for indicated use in late pregnancy. ANGUSTA® should only be used prior to 37 weeks gestation if clinically indicated and should not be used at any other time during pregnancy since a threefold increased risk of foetal malformations has been reported in pregnancies exposed to misoprostol in first trimester. No studies have been performed to investigate the amount of misoprostol acid in colostrum or breast milk. Misoprostol has been detected in human milk following oral administration of misoprostol in tablet form. Negligible amounts remain in maternal plasma after 3.75 hours and even lower concentrations will remain in breast milk. Breast-feeding can start 4 hours after the last dose of ANGUSTA®.

Undesirable Effects: The following adverse reactions have been reported: Very common (≥1/10): nausea, vomiting, meconium stain, postpartum haemorrhage. (Common (≥1/100 to <1/10): diarrhoea, uterine hyperstimulation, chills, pyrexia; neonatal: Apgar score low, foetal heart rate abnormal.

Marketing Authorisation Number: PL 20011/0072

Marketing Authorisation Holder: Norgine Pharmaceuticals Ltd., Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge UB9 6NS.

ATC Code: G02AD06.

Price and pack sizes: Price and pack sizes vary according to country.

Legal Category: Prescription Only Medicine.

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ANGUSTA® has varying availabilities and licensing internationally. Before prescribing, consult your country approved prescribing information, available from your local distributor or Norgine Limited.

Adverse events should be reported to your regulatory agency. Adverse events should also be reported to your local distributor or Norgine Limited, Norgine House, Moorhall Road, Harefield, Uxbridge, Middlesex, UB9 6NS, United Kingdom. Email: globalmedinfo@norgine.com