سونوسونو™ مادة فرز 2 لإعداد سطوح للتصريف سطوح الطقس سونوسونو™ مادة فرز

الوصف

مادة الفرز 2 لإعداد سطوح
مادة فرز لإعداد سطوح الطقس للتصريف. مطلوب لطبقات الحماية تحت الأسطح الخرسانية المكشوفة وتحت الأغشية الأسفلتية المكشوفة. مطابق لمعايير ASTM D 4258 و ASTM D 4263 و ASTM D 4259.

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شكل الصيانة/ كمية العلبة بالرطل
مادة فرز 2 لإعداد سطوح للتصريف/ علبة بالرطل
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مادة فرز 2 لإعداد سطوح للتصريف/ العلامات التجارية
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مادة فرز 2 لإعداد سطوح للتصريف/ معلومات
مادة فرز 2 لإعداد سطوح للتصريف/ معلومات

Syntocinon® concentrate for solution for infusion / Syntocinon® nasal spray

Composition:
Active substance: Oxytocin
Excipients:
Concentrate for solution for infusion / solution for injection: Sodium chloride, water for injections, acid glacial, chlorobutanol, ethanol 96% v/v, water for injections.
Nasal spray: E 216, E 218 and chlorobutanol hemihydrate for preservation, water for injections.
Information might differ in some countries.

Pharmaceutical form and quantity of active substance per unit
Concentrate for solution for infusion / solution for injection: 1 ml contains 5 I.U. oxytocin.
Concentrate for solution for infusion / solution for injection: 1 ml contains 10 I.U. oxytocin.
Nasal spray: 1 ml contains 40 IU oxytocin.

Indications / Potential uses
Concentrate for solution for infusion / solution for injection (parenteral administration):

Antiparturition:
Induction of labour for medical reasons (e.g. postmaturity, premature rupture of the membranes, pre-eclampsia).
Induction of labour for elective abortion (intra-amniotic).
Syntocinon may also be indicated in the early stages of pregnancy as an adjunctive therapy for the management of incomplete, inevitable or missed abortion.

Postparturition:
Caesarean section but not until after delivery of the child.
Prophylaxis and treatment of postpartum atonic uterine haemorrhage.
Nasal spray:
Stimulation of milk ejection and prevention of mastitis.

Dosage / Administration
Concentrate for solution for infusion / solution for injection (parenteral administration):
Depending on the indication, Syntocinon may be administered by the intravenous (i.v.), as an infusion or
Intramuscular or intravenous (i.m./i.v.) route.

1. Continuous infusion for induction or augmentation of labour:
Syntocinon is administered as an intravenous (i.v.) drip infusion in a suitable infusion solution (see Incompatibilities). Depending on the type of the continuous infusion, see Instructions for use and handling.
Close monitoring of the infusion rate is essential. The initial rate should be 1 ml = 2 mU/minute (= 0.1 to 0.2 mU/minute, or 0.5 to 4 drops/minute). It may be increased gradually – under close control of the response of the uterus – in steps of 1 mU/minute (= 2 drops/minute) at intervals of no less than 20 minutes and to no more than 1 to 2 mU/minute until a contraction pattern similar to that of normal labour is established. In most women, this rate will, this can often be achieved with an infusion of less than 18 mU/minute (= 9 mU/minute, or 20 drops/minute). The maximum recommended infusion rate is 20 mU/minute (= 2 mU/minute, or 40 drops/minute). In exceptional cases where higher infusion dose rates are required, the administration of Syntocinon should be stopped at an earlier stage of pregnancy when the uterus is less sensitive to oxytocin. It is advisable to use a more concentrated Syntocinon infusion (10 I.U. in 500 ml) in such cases.
When using a variable-speed infusion pump instead of drip infusion, the appropriate concentration of the solution for the recommended dosage range must be calculated according to the specifications of the pump.
The dosage, strength and duration of contractions and also the fetal heart rate must be carefully monitored throughout the infusion. Once an adequate level of uterine activity is attained, the infusion rate can often be reduced to a maintenance dosage (see Dosage, Section 2).

Postparturition:
Caesarean section but not until after delivery of the child.
Prophylaxis and treatment of postpartum atonic uterine haemorrhage.
Nasal spray:
Stimulation of milk ejection and prevention of mastitis.

Dosage / Administration
Concentrate for solution for infusion / solution for injection (parenteral administration):
Depending on the indication, Syntocinon may be administered by the intravenous (i.v.), as an infusion or
Intramuscular or intravenous (i.m./i.v.) route.

2. Direct infusion for postpartum use (the composition of the direct infusion, see Instructions for use and handling):
Intramuscular:
5.0 I.U. as 1 ml ampoule (= infusion solution) immediately after delivery of the child.
Prevention of postpartum uterine haemorrhage:
5.0 I.U. as 1 ml ampoule (= infusion solution) immediately after expulsion of the placenta. As an alternative, 5 to 10 IU may be administered by slow intravenous injection (over a period of at least 1 minute) or 5 to 10 IU may be administered by intramuscular injection. If the uterine response is insufficient, an intravenous infusion may be administered.
Treatment of postpartum uterine haemorrhage:
5 IU as a 1-minute i.v. infusion, or 5 to 10 IU i.m., followed in severe cases by i.v. infusion of 5 to 10 IU.
Alternatively, 5 IU as a 1-minute bolus injection, at the rate necessary to control uterine atony.
Bolus intramyofiral (subserous) injection of oxytocin is not harmful.
Caution:
Over-stimulation of the uterus (0.5 I.U. per nasal spray solution containing 4 I.U. oxytocin) in one nostril 5 minutes before the infant is put to the breast may inhibit milk ejection.

Special dosage recommendations
Paediatric female patients: Syntocinon has only been studied in female patients of childbearing age. Safety and efficacy in children and adolescents. The dosage recommendations can be given for use in pregnancies in adolescents aged <18 years owing to a lack of evidence.
Elderly female patients: There is no indication in post-menopausal women.
Renal impairment: No studies have been performed in renally impaired patients. Owing to the renal excretion of oxytocin and its antibiotic properties, accumulation is to be anticipated in patients with renal impairment. Therefore, Syntocinon should be used with particular caution in patients with renal impairment.
Hepatic impairment: No studies have been performed in hepatically impaired patients. No dosage recommendations can therefore be made.

Instructions for use/ Use/ Instructions for use and handling (*under Dosage / Administration*)

Contraindications
Hypertonic uterine contractions; fetal distress (unless delivery is imminent).
Severe toxaemia; predisposing factors for amniotic fluid embolism (intrauterine fetal death, placental abruption).
Contracted pelvis; if fetal life is not considered viable, spontaneous labour must be awaited and/or vaginal delivery is contraindicated, (e.g., significant cephalopelvic disproportion, fetal malpresentation, placenta praevia, uterine rupture, severe cervical dystocia, severe anteroposterior or primipara, overdilatation or reduced resistance of the cervix, cervical cancer, active genital herpes, uterine myomata, multiparity involving more than four births, multiparity in older women, previous uterine surgery, previous history of a few hours Remedies of an increased risk SO IS AS AS AS Antiretroviral.
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Hepatic impairment: No studies have been performed in hepatically impaired patients. No dosage recommendations can therefore be made.

Instructions for use/ Use/ Instructions for use and handling (*under Dosage / Administration*)

Contraindications
Hypertonic uterine contractions; fetal distress (unless delivery is imminent).

When Syntocinon is given to induce or augment labour, the following must be borne in mind:
- Oxytocin administered with oxytocin should be administered only when clearly indicated for medical reasons, and not for reasons of convenience.
- Syntocinon must only be administered as a continuous i.v. infusion, and never by i.v. jet, or i.v. bolus injection.
- Oxytocin should be given by slow i.v. infusion, preferably by slow exsanguination, which may cause fetal distress, asphyxia and death, particularly if the uterine response to oxytocin is excessive.
- Particular caution is required in the presence of borderline cephalopelvic disproportion, uterine hypertonicity, fetal distress, moderate hypotension, cardiac disorders or previous lower uterine segment caesarean sections, and in patients over 35 years of age.
- Concomitant use of other uterotonic substances (including prostaglandins) or other medicinal products or oxytocin pharmacodynamically potentiate the risk of postpartum disseminated intravascular coagulation (DIC).
- Concomitant use of oxytocin and other medicinal products or substances that may cause hypotension or tachycardia should be avoided.
- Oxytocin should be used with particular caution in patients with a history of cardiovascular disease (such as hypertensive cardiopathy, coronary artery disease, cardiac decompensation, cardiac arrhythmias) to avoid substantial changes in blood pressure and heart rate.
- Oxytocin should be used with particular caution in patients with known long QT syndrome or other risk factors for QT prolongation, including contraindication with medicinal products for which there is a known risk of QT prolongation (see "Interactions").

To avoid these rare complications, the following precautions must be taken: intravenous high doses of oxytocin are given over prolonged periods.
An electrolyte infusion solution (not a glucose solution) should be used; the volume of infused fluid should be kept as low as possible (e.g. 1 litre per day); the fluid balance must be monitored; the urine should be restricted; the fluid balance should be monitored; and serum electrolytes should be measured if changes in electrolyte levels are suspected.
In patients with severe hepatic or renal impairment, there is an increased risk of water retention or accumulation of oxytocin. Therefore, the fluid balance should be monitored and the urine should be restricted; the fluid balance should be monitored; and serum electrolytes should be measured if changes in electrolyte levels are suspected.
Syntocinon must not be administered within 6 hours after vaginal prostaglandin E2 and within 4 hours after PGF2α.
Hypersensitivity to the active substance or to any of the excipients indicated under "Composition".
Contraindications for oxytocin include: uterine hypertonicity; unstable hypotension; cardiac disorders or previous lower uterine segment caesarean sections, and in patients over 35 years of age.
Concomitant use of other uterotonic substances (including prostaglandins) or other medicinal products or oxytocin pharmacodynamically potentiate the risk of disseminated intravascular coagulation (DIC).
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Oxytocin should be used with particular caution in patients with known long QT syndrome or other risk factors for QT prolongation, including contraindication with medicinal products for which there is a known risk of QT prolongation (see "Interactions").

Warnings and precautions
Oxytocin should be administered under hospital conditions and with qualified medical supervision.
Intravenous (i.v.) bolus injection should not be avoided, as it may result in severe hypotension and death.
Oxytocin should be used with particular caution in patients with coronary artery disease (such as ischemia, myocardial infarction, coronary spasm) to avoid substantial changes in blood pressure and heart rate.
Oxytocin should be used with particular caution in patients with known long QT syndrome or other risk factors for QT prolongation, including contraindication with medicinal products for which there is a known risk of QT prolongation (see "Interactions").
There are insufficient data regarding possible interactions between Syntocinon and sympathomimetics in epidural or spinal anaesthesia. Concomitant administration is not recommended.
Oxytocin may enhance the pressor effect of vasoconstrictors and sympathomimetics. This also applies to vasoconstrictors contained in local anaesthetic preparations.
Antihypertensives: Oxytocin may potentiate the effects of antihypertensive drugs. Patients undergoing concomitant treatment with ganglionic or adrenergic neuron blockers particularly carefully.

Pregnancy / Breast-feeding
There is no indication for oxytocin in pregnancy, except for medically induced abortion and the augmentation of labour, and over inappropriately or indicated abortion.
There is clear evidence of risks to the human fetus, including fetal death, asphyxia, CNS and/or brain damage and intracranial hemorrhage.
There have been no reproductive studies of oxytocin in animals.
Oxytocin is excreted in human milk in very small quantities.
Small amounts of oxytocin are reported in the breast milk; no adverse effects are expected in the infant.

Effects on ability to drive and use machines
No relevant studies have been carried out. Syntocinon can induce labour. As women with uterine contractions should not drive or use machines, no recommendation can be made for the use of Syntocinon. The ability to drive and to use machines may also be limited by possible adverse effects of oxytocin, such as changes in blood pressure or blood pressure.

Adverse effects
The serious adverse effects of oxytocin are described in the "Warnings and precautions" section, in particular, these are:
In infants: and augmentation of labour, i.v. infusion of excessive doses results in uterine overstimulation, which may cause fetal distress, fetal asphyxia, and in severe cases, intracranial fetal death, or uterine hypotonicity, uterine contractions and rupture of the uterus.
In the case of the route of administration, the following adverse effects have been reported in the outlines:

Frequencies:
Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (*annoyed; based on spontaneous post-marketing reports; precise frequency cannot be estimated.*

Blood and lymphatic system disorders
Not known: Disseminated intravascular coagulation.
Immune system disorders
Rare: anaphylactic / anaphylactoid reactions (associated with oxytocins, hypotension) anaphylactic / anaphylactoid shock.
Hypersensitivity must be discontinued immediately if such reactions occur.
Not known: Angioedema (only observed on parenteral application).
Eye disorders
Nasal spray allergic dermatitis.
Vascular disorders
Not known: Water intoxication, maternal hypovolaemia.
Nervous disorders
Common: headache.
Cardiac disorders
Not known: Tachycardia, bradycardia.
Uncommon: Arrhythmia (see "Warnings and precautions" and "Interactions").
Not known: Myocardial ischaemia, ECG prolongation.
Vascular disorders
Very rare: Hypertension.
Respiratory disorders
Respiratory, thoracic and mediastinal disorders
Not known: Flatus dissenchyma, acute pulmonary oedema.
Gastrointestinal disorders
Common: Nausea, vomiting.
Skin and subcutaneous tissue disorders
Rare: Rash.
Reproductive system and breast disorders
Uncommon: Nasal spray: abnormal uterine contractions.
Not known: Uterine hypotonicity, tetanic contractions, rupture of the uterus.
General disorders and administration-site conditions that known
Rare: Chest pain.
Adverse effects in the fetus / newborn
Manipulation and nutrition disorders
Not known: Water intoxication, hyponatraemia.
Cardiac disorders
Not known: Fetal distress, asphyxia (possibly with a fatal outcome).

Interactions
The symptoms and consequences of overdose correspond to the adverse effects described above. In addition, cases of placental abruption and/or acute fetal distress have been reported.

Management: When signs or symptoms of overdose occur during i.v. infusion of Syntocinon, the infusion must be discontinued immediately. Oxytocin must be administered in a hospital setting. Antidote does not exist. It is recommended to give oxygen to the mother. In the event of water intoxication, it is important to restrict the fluid intake and to administer a diuretic and electrolytes. Patients should also be monitored for possible convulsions.

Properties / Actions
ATC code: H01BB02

Mechanism of action
The mode of action of oxytocin or Syntocinon is a synthetic nonapeptide identical to the posterior pituitary hormone. Oxytocin is released primarily towards the end of pregnancy and postpartum, and its concentration increases in labour.
As the number of oxytocin receptors in the uterus increases during pregnancy, oxytocin stimulates the smooth muscle of the uterus (myometrium) and the cells of the mammary glands (cells of the myoepithelial postpartum).
Oxytocin stimulates, in a volume-dosing quantities, oxytocin receptors in the uterine contractions in the upper segment of the uterus, increasing the frequency, strength and duration in three observed during contractions in labour.
Oxytocin has a rapid onset of action, with a latency period of less than 1 minute after intravenous (i.v.) injection and 2 to 3 minutes following i.m. administration.
The duration of effect is 30 to 60 minutes following i.m. injection; it is shorter following i.v. injection.
When Syntocinon is given by i.v. infusion at doses appropriate for induction or augmentation of labour, the uterine response rate in women with a fetal weight of 2.5 kg or more is approximately 90% in nulliparous and approximately 95% in multiparous.
Levels of oxytocin are comparable to those measured in the first stage of spontaneous labour.
Upon discontinuation of the infusion, or following a substantial reduction in the infusion rate, e.g. in the event of overstimulation, uterine activity ceases within 30 to 60 minutes in most women.
Desensitization of oxytocin receptors has been observed with prolonged exposure in vitro.
Following i.v. bolus injection of the uterus, oxytocin facilitates the release of milk and cells toward reaching by contracting the myoepithelial cells surrounding the mammary alveoli. It does not, however, possess any galactogenic action.

Synthetic oxytocin does not contain vasopressin, but still possesses weak intrinsic vasopressor-like antidiuretic activity.
Oxytocin has a direct stimulating effect on uterine smooth muscle. Particularly when high doses are injected rapidly by the intravenous route, little can cause hypotension, flushing and reflex tachycardia, which are transient and dose-dependent.

Pharmacokinetics
Absorption
After intramuscular injection, oxytocin is rapidly absorbed from the muscle tissue. Plasma levels of oxytocin following intravenous infusions of 40 U/min (a pregnant woman at term was 2 to 5 mU/min, respectively) reach a plateau and sufficiently and adequate from nasal mucosa.
Distribution
The half-life and volume of distribution determined in 6 healthy men after i.v. injection was 232 (Max 35.8 to 20.7 Min) and 9.7 (Max 6.4 to 13.1) L, respectively. Oxytocin is distributed to the extracellular space, placental barrier in both directions. It may be bound in small quantities in the blood cells.
Metabolism
Oxytocin is a glycopeptide oxytocinase that is produced during pregnancy and appears in the plasma. It is produced by both the mother and the fetus. Oxytocinase is the hormone-specific enzyme for the inactivation of oxytocin and is produced in the placenta and liver. The metabolic clearance rate is approx. 20 mU/kg/minute in pregnant women.
Elimination
The plasma half-life of oxytocin ranges from 3 to 20 minutes. Oxytocin is excreted primarily in the form of metabolites in urine, less in bile and in milk.
Pharmacokinetics in special patient populations:
Renal impairment
No data are available.
Clearance/bioavailability of the infusion, or following a substantial reduction in the infusion rate, e.g. in the event of overstimulation, uterine activity ceases within 30 to 60 minutes in most women.
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Hepatic impairment
No data are available.
Synthetic oxytocin has not been studied in patients with hepatic impairment. However, as the enzyme responsible for metabolism is oxytocinase (including relevant activity in the placenta), no significant effect on oxytocin pharmacokinetics is expected in mild and moderate hepatic impairment. For severe hepatic impairment, see "Warnings and precautions".

Preclinical data
Preclinical data for oxytocin reveal no special risk for humans based on conventional studies of single-dose acute toxicity, genotoxicity and mutagenicity.

Mutagenicity / carcinogenicity
No long-term studies have yet been carried out to determine the genotoxicity and mutagenicity of oxytocin. Tests were negative for chromosomal aberration and sister chromatid exchange in human peripheral lymphocytes and in Chinese hamster ovary cells in vitro and in the bone marrow of mouse. Oxytocin had no genotoxic properties. The genotoxic potential of oxytocin has not been determined in vivo.
No long-term studies are available.

Reproductive toxicity
Treatment of rats with oxytocin in early pregnancy of doses in excess of the maximum recommended human dose caused embryonic lethal in one study.
No standard teratogenicity or fertility studies with oxytocin are available.

Other information
Incompatibilities
Do not use after the expiry date (= EXP) printed on the pack.
Syntocinon should not be diluted and should not be used for longer than 1 month. It is therefore recommended to note the date of opening on the label of the bottle.

Special precautions for storage
Keep out of the reach of children.
Keep refrigerated (2 to 8°C) for infusion / solution for injection. Store in a refrigerator (2 to 8°C).
Nasal spray: Store in a refrigerator (2 to 8°C).
Once opened, the bottle should be stored at room temperature (15 to 25°C).

Instructions for use and handling
Nasal spray: The patient should preferably use the nasal spray when upright.
The flip-off cap must be removed. Before the spray is used for the first time, the pump must be primed by pressing the pump actuator three times until the spray solution is released. Holding the bottle upright, the nozzle must be inserted into one nostril, and the actuator depressed while inhaling gently through the nose.

Preparation of the continuous infusion:
For continuous infusion, dilute 5 IU Syntocinon with 500 ml of a physiological electrolyte solution (such as Ringer's solution). Ready-to-use solution contains 10 mU/ml. For patients in whom sodium may not be used, 5% glucose solution may be used instead (see "Warnings and precautions"). Ready-to-use solution contains 10 mU/ml. Whichever the bottle or bag must be inverted several times before use.

Preparation of the short infusion:
For short infusion, dilute 5 IU Syntocinon with 50 ml bag to a maximum of 100 ml of a physiological electrolyte solution (such as 0.9% saline). This solution contains 100 mU/ml 500 mililitri. For patients in whom sodium may not be used, 5% glucose solution may be used instead (see "Warnings and precautions"). To ensure even mixing of the solution for infusion, the bottle or bag must be inverted several times before use.

Pack size
Consult specific pack sizes.

Marketing
Marketing Authorisation
Not applicable.

Information last revised
May 2018

® = registered trademark

BSP Products GmbH, Neuhofstrasse 27, 6341 Baar, Switzerland

This is a medicine.
Medicines are a special product which affects your health, and its consumption creates its contractions in dangerous for you.
Medicines should be used only according to the prescription and the instructions of the pharmacist who sold the medicament.
Medicines should be pharmacist-are experts in medicine, its benefits and risks.
Do not by yourself interrupt the period of treatment prescribed for you.
Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children.

Council of Arab Health Ministries
Union of Arab Pharmacists

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