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SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

SYNTOCINON 5 IU® Injection

SYNTOCINON 10 IU® Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

SYNTOCINON 5 IU®:

Each 1 ml ampoule (concentrate for solution for infusion, solution for injection)

contains: 5 IU synthetic oxytocin.

Preservative: Chlorobutanol 0,5% *m/v*.

This medicine contains 2,99 mg (0,13 mmol), less than 1 mmol sodium (23 mg)

per 1 ml that is to say essentially 'sodium free'.

Sugar free.

SYNTOCINON 10 IU®:

Each 1 ml ampoule (concentrate for solution for infusion, solution for injection)

contains: 10 IU synthetic oxytocin.

Preservative: Chlorobutanol 0,5% *m/v*.

This medicine contains 2,99 mg (0,13 mmol), less than 1 mmol sodium (23 mg) per 1 ml that is to say essentially 'sodium free'.

Sugar free.

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For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

SYNTOCINON 5 IU®

A clear, colourless solution in a 1 ml clear glass ampoule coded with a single magenta-coloured ring on the neck of the ampoule.

SYNTOCINON 10 IU®

A clear, colourless solution in a 1 ml clear glass ampoule, coded with two magenta- coloured rings on the neck of the ampoule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Antepartum:

- Induction of labour for medical reasons, e.g. in case of post-term gestation, premature rupture of the membranes, or pregnancy-induced hypertension (pre-eclampsia).
- Enhancement of labour in selected cases of uterine inertia.
- SYNTOCINON may also be indicated in early stages of pregnancy, as adjunctive therapy for the management of incomplete, inevitable or missed abortion.

Postpartum:

- During a caesarean section, after the delivery of the child.

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- Prevention and treatment of postpartum haemorrhage and uterine atony.

4.2 Posology and method of administration

Posology

Induction or enhancement of labour:

SYNTOCINON should be administered as an intravenous drip infusion or, preferably, by means of a variable-speed infusion pump. For drip infusion, it is recommended that 5 IU of SYNTOCINON be added to 500 ml of a physiological electrolyte solution (such as sodium chloride 0,9 %). For patients in whom infusion of sodium chloride must be avoided, 5 % dextrose solution may be used as the diluent *(see section 4.4).*

To ensure even mixing, the bottle or bag must be turned upside-down several times before use.

The initial infusion rate should be set at 1 to 4 milliunits/minute (0,1 to 0,4 ml/min or 2 to 8 drops/minute). It may be gradually increased at intervals not shorter than 20 minutes until a contraction pattern similar to that of normal labour is established. In pregnancy near term, this can often be achieved with an infusion of less than 10 milliunits/minute (1 ml/minute or 20 drops/minute), and the recommended maximum rate is 20 milliunits/min (2 ml/minute or 40 drops/minute). In the unusual event of higher rates being required, as may occur in the management of foetal death *in utero* or for induction of labour at an earlier stage of pregnancy, when the uterus is less sensitive to oxytocin, it is advisable to use a more concentrated SYNTOCINON solution, e.g. 10 IU in 500 ml.

When using a motor-driven infusion pump which delivers smaller volumes than those

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given by drip infusion, the concentration suitable for infusion within the recommended dosage range must be calculated according to the specifications of the pump.

The frequency, strength and duration of contractions, as well as the foetal 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. In the event of uterine hyperactivity and/or foetal distress, the SYNTOCINON infusion must be discontinued immediately.
If, in women who are at term or near term, regular contractions are not established after the infusion of a total amount of 5IU SYNTOCINON, it is recommended that the attempt to induce labour should be terminated; it may be repeated on the following day, starting again from a rate of 1 to 4 milliunits/minute (0,1 to 0,4 ml/minute or 2 to 8 drops/minute).

Note: Inadvertent paravenous infusion of SYNTOCINON is not harmful.

Caesarean section:

5 IU by IV infusion (5 IU diluted in physiological electrolyte solution and administered as an IV drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes) immediately after delivery of the foetus.

Prevention of postpartum uterine haemorrhage:

The usual dose is 5 IU by intravenous infusion (5 IU diluted in physiological electrolyte solution and administered as an IV drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes) or 5 to 10 IU intramuscular after delivery of the placenta. In women given SYNTOCINON for induction or enhancement of labour, the

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infusion should be continued at an increased rate during the third stage of labour and for the next few hours thereafter.

Treatment of postpartum uterine haemorrhage:

5 IU by infusion (5 IU diluted in physiological electrolyte solution and administered as an IV drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes) or 5 to 10 IU IM, followed in severe cases by intravenous infusion of a solution containing 5 to 20 IU of SYNTOCINON in 500 ml of an electrolyte-containing diluent, run at the rate necessary to control uterine atony.

Incomplete, inevitable, or missed abortion:

5 IU by intravenous infusion (5 IU diluted in physiological electrolyte solution and administered as an IV drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes). If necessary, followed by intravenous infusion at a rate of 20 to 40 milliunits/minute or higher.

Method of administration

- When SYNTOCINON is given for caesarean section, treatment of postpartum uterine haemorrhage or incomplete, inevitable, or missed abortion: SYNTOCINON should be administered as an IV drip infusion or, preferably, by means of a variable-speed infusion pump.
- When SYNTOCINON is given for prevention of postpartum uterine haemorrhage: SYNTOCINON should be administered as an IV drip infusion or, preferably, by

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means of a variable-speed infusion pump or intramuscular after delivery of the placenta.

- When SYNTOCINON is given for induction and enhancement of labour:

  SYNTOCINON must only be administered as an intravenous infusion, and never by subcutaneous, intramuscular or intravenous bolus injection *(see section 4.4)*.

4.3 Contraindications

- Known hypersensitivity to oxytocin or to any of the excipients of SYNTOCINON.
- Hypertonic uterine contractions, foetal distress when delivery is not imminent.
- Any conditions in which, for foetal or maternal reasons, spontaneous labour is unadvisable and/or vaginal delivery is contra-indicated: e.g.:
  - significant cephalopelvic disproportion;
  - foetal malpresentation;
  - placenta praevia and vasa praevia;
  - placental abruption;
  - cord presentation or prolapse;
  - overdistension or impaired resistance of the uterus to rupture as in multiple pregnancy;
  - polyhydramnios;
  - grand multiparity;
  - in the presence of uterine scars resulting from major surgery, including classical caesarean section.

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4.4 Special warnings and precautions for use

Induction of labour

When SYNTOCINON is given for induction and enhancement of labour:

- The induction of labour by means of SYNTOCINON should be attempted only when strictly indicated for medical reasons rather than for convenience. Administration should only be under hospital conditions and qualified medical supervision.
- SYNTOCINON must only be administered as an intravenous infusion, and never by subcutaneous, intramuscular or intravenous bolus injection *(see section 4.2)*.
- Foetal distress and foetal death: Administration of SYNTOCINON at excessive doses results in uterine overstimulation which may cause foetal distress, asphyxia and death, or may lead to hypertonicity, tetanic contractions or rupture of the uterus. Careful monitoring of foetal heart rate and uterine motility (frequency, strength, and duration of contractions) is essential, so that the dosage may be adjusted to individual response.
- Caution is required in the presence of borderline cephalopelvic disproportion, secondary uterine inertia, mild or moderate degrees of pregnancy-induced hypertension, cardiac disease and in patients above 35 years of age or with a history of lower-uterine-segment caesarean section.
- Disseminated intravascular coagulation: The pharmacological induction of labour using uterotonic medicines such as oxytocin as contained in SYNTOCINON, increases the risk of post-partum disseminated intravascular coagulation (DIC). The pharmacological induction itself, and not a particular medicine, is linked to such risk. This risk is increased in particular if the woman has additional risk factors for DIC such as being 35 years of age or over, complications during the pregnancy and

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gestational age more than 40 weeks. In these women, SYNTOCINON should be used with care, and the doctor should be alerted by signs of DIC.

- SYNTOCINON should not be used for prolonged periods in patients with oxytocin-resistant uterine inertia, severe pre-eclamptic toxaemia or severe cardiovascular disorders.

Intrauterine death

In the case of foetal death *in utero,* and/or in the presence of meconium-stained amniotic fluid, tumultuous labour must be avoided, as it may cause amniotic fluid embolism.

Cardiovascular disorders

SYNTOCINON should be used with caution in patients who have a pre-disposition to myocardial ischaemia due to pre-existing cardiovascular disease (such as hypertrophic cardiomyopathy, valvular heart disease and/or ischemic heart disease including coronary artery vasospasm), to avoid significant changes in blood pressure and heart rate in these patients. Infusion volume should be low in patients with cardiovascular disorders.
SYNTOCINON should not be given as an IV bolus injection as it may cause an acute short-lasting hypotension accompanied with flushing and reflex tachycardia *(see section 4.2)*.

QT syndrome

SYNTOCINON should be given with caution to patients with known ‘long QT syndrome’ or related symptoms and to patients taking medicines that are known to prolong the QTc interval (*see section 4.5*).

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Water intoxication

Because SYNTOCINON possesses slight anti-diuretic activity, its prolonged intravenous administration at high doses in conjunction with large volumes of fluid (as may be the case in the treatment of inevitable or missed abortion or in the management of postpartum haemorrhage) may cause water intoxication associated with hyponatraemia. The combined antidiuretic effects of SYNTOCINON and the IV fluid administration may cause fluid overload leading to a hemodynamic form of acute pulmonary oedema without hyponatraemia.
To avoid these complications, the following precautions must be observed whenever high doses of oxytocin are administered over a long time: an electrolyte-containing diluent must be used (not dextrose); the volume of infused fluid should be kept low (by infusing oxytocin at a higher concentration than recommended for the induction or enhancement of labour at term); fluid intake by mouth must be restricted; a fluid balance chart should be kept and serum electrolytes should be measured when electrolyte imbalance is suspected.

SYNTOCINON should not be given parenterally at the same time as other oxytocics.

Anaphylactic reactions/structural homology with latex

Oxytocin shares structural homology with latex. There are reports of anaphylactic reactions after parenteral use of oxytocin in patients with latex allergy. There is probably a cross-sensitivity between oxytocin and latex. Therefore:

- A pre-existing latex allergy may increase the risk of anaphylactic reactions when using oxytocin.
- The use of oxytocin can lead to a corresponding sensitisation and thereby increase the risk of latex allergy.

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Should such a reaction occur, administration must be discontinued immediately.

Renal impairment

Caution should be exercised in patients with severe renal impairment because of possible water retention and possible accumulation of oxytocin.

Hepatic impairment

Caution should be exercised in patients with severe hepatic impairment because of possible water retention and possible accumulation of oxytocin.

4.5 Interaction with other medicines and other forms of Interaction

Prostaglandins and their analogues.

Prostaglandins and its analogues facilitate contraction of the myometrium and may potentiate the uterotonic effect of SYNTOCINON and vice versa; therefore, concomitant administration requires very careful monitoring.

Medicines prolonging the QT interval.

SYNTOCINON should be given with caution in patients taking medicines that are known to prolong the QTc interval, as there is an increased risk of QT prolongation.

Other uterotonics

There have been reports of ventricular tachycardia/ventricular fibrillation and myocardial infarction/cardiac arrest, some of which are fatal, in the treatment of postpartum atonic uterine bleeding with concomitant administration of sulprostone and/or oxytocin and/or

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methylergometrine.

Inhalation anaesthetics

Some inhalation anaesthetics (e.g., cyclopropane, halothane, sevoflurane or desflurane) have a relaxing effect on the uterus and produce a notable inhibition of uterine tone and therefore may diminish the uterotonic effects of oxytocin. These inhalation anaesthetics may enhance the hypotensive effect of SYNTOCINON and reduce its oxytocic action. Their concurrent use with SYNTOCINON has also been reported to cause cardiac rhythm disturbances.

Vasoconstrictors/ Sympathomimetics

SYNTOCINON may enhance the pressor effects of vasoconstrictors and sympathomimetics. This also applies to vasoconstrictors, which are contained in medicines for local anaesthesia.

Caudal anaesthetics

When given during or after caudal block anaesthesia, SYNTOCINON may potentiate the pressor effect of sympathomimetic vasoconstrictor medicines.

Antihypertensives

SYNTOCINON can increase the effect of antihypertensives. Therefore, patients should be monitored particularly carefully during concomitant administration.

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4.6 Fertility, pregnancy, and lactation

Women of childbearing potential/ Contraception in males and females

Not applicable.

Pregnancy

Animal reproduction studies have not been conducted with SYNTOCINON. Based on extensive experience with oxytocin, its chemical structure and pharmacological properties, it is unlikely to present a risk of foetal abnormalities when used as indicated.

Breastfeeding

SYNTOCINON may be found in small quantities in a mother's breast milk. However, it is unlikely to cause harmful effects in the newborn because it is inactivated in the alimentary tract.

Fertility

Not applicable.

4.7 Effects on ability to drive and use machines

SYNTOCINON can induce labour, therefore caution should be exercised when driving or operating machines. Women with uterine contractions should not drive or use machines.

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4.8 Undesirable effects

a. Summary of the safety profile

- When SYNTOCINON is used by IV infusion for the induction or enhancement of labour, its administration at excessive doses results in uterine overstimulation which may cause foetal distress, asphyxia and death, or may lead to hypertonicity, tetanic contractions or rupture of the uterus.
- Prolonged or too rapid infusion of SYNTOCINON has an antidiuretic effect, which may cause transient water intoxication *(see section 4.4)*.
- With either mode of administration, SYNTOCINON may cause the following undesirable effects:
  - Pelvic haematomas, neonatal jaundice and retinal haemorrhage have been associated with the use of SYNTOCINON.
  - Maternal death from severe hypertension and subarachnoid haemorrhage has occurred.
  - Postpartum haemorrhage and fatal afibrinogenaemia have been reported and may be due to obstetric complications.

b. Tabulated list of adverse reactions

Body System	Undesirable effect		
	Frequent	Less frequent	Frequency not known

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Blood and the lymphatic system disorders			Disseminated intravascular coagulation.
Immune system disorders		Anaphylactoid reactions (associated with dyspnoea, hypotension), anaphylactic/ anaphylactoid shock.	Angioedema (observed only with parenteral administration).
Metabolism and nutrition disorders			Water intoxication, maternal hyponatraemia, neonatal hyponatraemia.
Nervous system disorders	Headaches		
Cardio-vascular disorders	Tachycardia, bradycardia, hypotension, shock, flushing.	Arrhythmias, hypertension.	Myocardial ischaemia, QTc prolongation, hypotension, hot flushes (flushing),

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			"foetal distress", asphyxia (up to fatal outcome).
Respiratory, thoracic and mediastinal disorders			Acute pulmonary oedema.
Gastrointestinal disorders	Nausea, vomiting		
Skin and subcutaneous tissue disorders		Rash	
Uro-genital system disorders			Hypertonicity, tetanic contractions or rupture of the uterus.

Description of selected adverse reactions

- Water intoxication associated with maternal and neonatal hyponatraemia has been reported in cases where high doses of SYNTOCINON have been administered together with large amounts of electrolyte-free fluid over a prolonged period. *(see section 4.4).*
- The combined antidiuretic effect of SYNTOCINON and the IV fluid administration

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may cause fluid overload leading to a haemodynamic form of acute pulmonary oedema without hyponatraemia *(see section 4.4).*

- Rapid intravenous bolus injection of SYNTOCINON at doses amounting to several IU may result in acute short-lasting hypotension accompanied with flushing and reflex tachycardia (*see section 4.4*). These rapid haemodynamic changes may result in myocardial ischaemia, particularly in patients with pre-existing cardiovascular disease. Rapid IV bolus injection of SYNTOCINON at doses amounting to several IU may also lead to QTc prolongation.
- The pharmacological induction of labour using uterotonic medicines, including SYNTOCINON, increases the risk of postpartum disseminated intravascular coagulation (i.e. the absolute risk attributable to induction is 6 in 10 000) *(see section 4.4)*.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Symptoms:

- In overdose, side effects can be precipitated and/or be of increased severity (*see section 4.8)*.

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- In addition, because of uterine overstimulation, placental abruption and/or amniotic fluid embolism have been reported.
- Overdosage following prolonged or too rapid infusion, may give rise to the following complications: foetal distress (bradycardia and dysrhythmias, meconium staining of amniotic fluid or foetal asphyxia).
- Uterine hypertonicity, tetanic contraction, uterine rupture, extensive laceration of soft tissue, subarachnoid haemorrhage, severe hypotension, water retention and intoxication with convulsions, coma and even foetal and maternal death.

Treatment:

- When signs or symptoms of overdosage occur during continuous IV administration of SYNTOCINON, the infusion must be discontinued at once and oxygen should be given to the mother.
- In the event of water intoxication, it is essential to restrict fluid intake, promote diuresis, correct electrolyte imbalance, and control possible convulsions by judicious use of diazepam.
- Treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Oxytocin and analogues.

ATC code: H01BB02.

Mechanism of action

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The active substance oxytocin is a synthetic nonapeptide identical to oxytocin, a hormone released by the posterior lobe of the pituitary.

Oxytocin exerts a stimulatory effect on the uterine smooth muscle, particularly towards the end of pregnancy, during labour, after delivery and in the puerperium, i.e. at times when the number of specific oxytocin receptors in the myometrium is increased.

Pharmacodynamic effects

When given by low-dose intravenous infusion, oxytocin elicits rhythmic uterine contractions that are indistinguishable in frequency, force and duration from those observed during spontaneous labour.

At higher infusion dosages, or when given by single injection, the substance can cause sustained tetanic contractions.

Being synthetic, oxytocin does not contain vasopressin, but even in its pure form oxytocin possesses some weak intrinsic vasopressin-like anti-diuretic activity.

Being synthetic, oxytocin does not contain vasopressin, but even in its pure form oxytocin possesses some weak intrinsic vasopressin-like anti-diuretic activity.

Another pharmacological effect observed with high doses of oxytocin, particularly when administered by rapid intravenous bolus injection, is a transient direct relaxing effect on vascular smooth muscle, resulting in brief hypotension, flushing and reflex tachycardia.

5.2 Pharmacokinetic properties

Plasma levels and onset/duration of effect:

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Intravenous infusion:

When oxytocin is given by continuous intravenous infusion at doses appropriate for induction or enhancement of labour, the uterine response sets in gradually and usually reaches a steady state within 20 to 60 minutes.

The corresponding plasma levels of oxytocin are comparable to those measured during spontaneous first-stage labour.

For example, oxytocin plasma levels in 10 pregnant women at term receiving a 4 milliunits per minute intravenous infusion were 2 to 5 microunits/ml.

Upon discontinuation of the infusion, or following a substantial reduction in the infusion rate, e.g. in the event of overstimulation, uterine activity declines rapidly, but may continue at an adequate lower level.

Intravenous injection and intramuscular injection:

When administered by intravenous or intramuscular injection for prevention or treatment of postpartum haemorrhage, oxytocin acts rapidly with a latency period of less than 1 minute by intravenous injection, and of 3 to 7 minutes by intramuscular injection. The oxytocic response lasts for 30 to 60 minutes after intramuscular administration; possibly less after intravenous injection.

Distribution:

Oxytocin distributes throughout the extracellular fluid, with minimal amounts reaching the foetus. The steady-state distribution volume determined in 6 healthy men after intravenous injection was 12,2 L or 0,17 l/kg. Plasma protein binding is very low.

Oxytocin may be found in small quantities in mother’s breast milk.

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Biotransformation:

A glycoprotein aminopeptidase, oxytocinase, is produced during pregnancy and appears in the plasma. It is capable of degrading oxytocin. Enzyme activity increases gradually until term approaches at which time it rises steeply to high levels. Enzyme activity then declines after delivery. Enzyme activity in the placenta and in the uterine tissue is also high during this period. There is little or no degradation of oxytocin by plasma for men, non-pregnant women, or cord blood.

Elimination:

The relative ease with which the rate and force of uterine contractions can be regulated by the intravenous infusion of oxytocin is due to the short half-life of oxytocin. Values reported by various investigators range from 3 to 20 minutes. Removal of oxytocin from plasma is accomplished mainly by the liver and the kidneys. The metabolic clearance rate amounts to about 20 ml/kg per minute in men as well as in pregnant women. Less than 1 % of a given dose is excreted unchanged in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The other ingredients in SYNTOCINON 5 IU and SYNTOCINON 10 IU are:

Acetic acid, glacial.

Chlorobutanol hemihydrate 0,5% *m/v* (as preservative).

Ethanol 96% *w/w* (alcohol as solvent).

Sodium acetate trihydrate.

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Water for injection.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

SYNTOCINON 5 IU®:

60 months when stored in a refrigerator at a temperature 2-8°C.

SYNTOCINON 10 IU®:

60 months when stored in a refrigerator at a temperature 2-8°C.

6.4 Special precautions for storage

Store in a refrigerator between 2 and 8 °C.

Protect from direct light.

6.5 Nature and contents of container

SYNTOCINON 5 IU®: Carton of 5 ampoules of 1 ml each.

SYNTOCINON 10 IU®: Carton of 5 ampoules of 1 ml each.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

Not applicable.

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7 HOLDER OF THE CERTIFICATE OF REGISTRATION

Viatris Healthcare (Pty) Ltd.

4 Brewery Street

Isando

Gauteng

1601

8 REGISTRATION NUMBER(S)

SYNTOCINON 5 IU®: H/19/1967

SYNTOCINON 10 IU®: H/19/1963

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20 April 2012

10 DATE OF REVISION OF TEXT

TBA