SUPRANE (desflurane) PRESCRIBING INFORMATION – Republic of Ireland

Name and composition: Suprane inhalation vapour, solution. Desflurane 100 % v/v **Indications**: Inhalation agent for induction and maintenance of anaesthesia in adults and maintenance in intubated infants and children under 12 years. Not recommended for induction in paediatrics. Dental anaesthesia restricted to hospitals / day care units only **Dosage and Route:** Inhalation via specific vaporiser designed for use with Suprane. Administration must be individualized based on patient's responses. *Induction.* In adults, starting concentration of 3% is recommended, increasing dose between 0.5-1.0% increments every 2-3 breaths. Inspired concentrations of 4-11% usually produces surgical anaesthesia in 2-4 minutes. Higher concentrations up to 15% may be used, in such cases administration of oxygen should be 30% or above. After induction with intravenous drugs, desflurane can be started at 0.5-1.0 MAC. Desflurane should be administered at 0.8 MAC or less, and in conjunction with a barbiturate induction and hyperventilation until cerebral decompression in patients with known or suspected increases in cerebrospinal fluid pressure. Attention to be paid to maintain cerebral perfusion pressure. *Maintenance.* 2-6% with concomitant nitrous oxide or 2.5-8.5% in oxygen or oxygen enriched air. Surgical levels of anaesthesia may be sustained with a reduced concentration of desflurane when nitrous oxide is used. 5.2-10% desflurane with or without nitrous oxide in children under 12 years of age or intubated infants. Up to 18% has been administered for short periods – ensure 25% oxygen for high concentrations with nitrous oxide. Desflurane is not approved for maintenance of anaesthesia in children 12-18 years of age. 1-4% in nitrous oxide/oxygen has been successful in chronic renal/hepatic impairment and renal transplant. **Side effects:** *See Summary of Product Characteristics for detail.* May cause a dose-dependent cardio-respiratory depression. *Very common:* Nausea, vomiting *Common*: Pharyngitis, breath holding, headache, conjunctivitis, nodal arrhythmia, bradycardia, tachycardia, hypertension, apnea, cough, laryngospasm, salivary hypersecretion, increased creatinine phosphokinase, ECG abnormalities *Other side effects:* Coagulopathy, hypokalaemia, hyperkalaemia, metabolic acidosis, agitation, dizziness, convulsions, ocular icterus, myocardial infarction, myocardial ischaemia, arrhythmia, cardiac arrest, Torsade de Pointes, ventricular failure, ventricular hypokinesia, atrial fibrillation, electrocardiogram QT prolonged, vasodilation, malignant hypertension, haemorrhage, hypotension, shock, hypoxia, respiratory arrest, respiratory failure, respiratory distress, bronchospasm, haemoptysis, pancreatitis acute, abdominal pain, hepatic failure, hepatic necrosis, hepatitis, cytolytic hepatitis, cholestasis, jaundice, abnormal hepatic function, liver disorder, urticaria, erythema, myalgia, rhabdomyolysis, hyperthermia malignant, asthenia, malaise, electrocardiogram ST-T change, electrocardiogram T wave inversion, transaminase increased, alanine aminotransferase increased, aspartate aminotransferase increased, blood bilirubin increased, coagulation test abnormal, ammonia increased, increased blood glucose levels, agitation postoperative, dizziness, migraine, tachyarrhythmia, palpitations, eye burns, blindness transient, encephalopathy, ulcerative keratitis, ocular hyperemia, visual acuity reduced, eye irritation, eye pain, fatigue, accidental exposure, skin burn sensation, drug administration error. **Precautions**: Only to be administered by people trained in general anaesthesia. All patients should be constantly monitored, including ECG, BP, oxygen saturation and end tidal carbon dioxide with appropriate emergency facilities for resuscitation available. Hypotension and respiratory depression increases with depth of anaesthesia. Use in hypovolaemic or hypotensive patients has not been extensively investigated. Not for use in patients prone to bronchoconstriction. Caution in repeated anaesthesia with halogenated agents in a short period of time. Desflurane causes a rise in blood sugar levels during anaesthesia. All necessary precautions should be taken to ensure carbon dioxide adsorbents are not allowed to dry out. Desflurane may trigger malignant hyperthermia. In such cases discontinue the triggering agents, administer dantrolene sodium and apply supportive therapy. Renal failure may appear later, monitor urine flow and sustain if possible. Fatal outcomes due to malignant hyperthermia have been reported. Inhaled anaesthetic agents has been associated with rare increases of potassium resulting in cardiac arrhythmias, some fatal. Patients with latent and overt muscular dystrophies, particularly Duchenne muscular dystrophy appear most vulnerable. Early and aggressive

intervention to treat hyperkalaemia and arrhythmias is recommended. Use with caution in children with asthma or history of recent upper airway infection. Not approved for maintenance in children 12-18 years of age. Not approved for non-intubated paediatric patients or non-intubated children. Caution in children with LMA, in particular for children 6 years old or younger. Children emerging from anaesthesia may experience brief state of agitation that may hinder cooperation. Caution when administering to patients susceptible to QT prolongation, very rarely associated with torsade de pointes. Disruption of hepatic function, icterus and fatal liver necrosis have been reported. May cause sensitivity hepatitis. Cirrhosis, viral hepatitis or other pre-existing hepatic disease may be a reason to select an alternative agent. Desflurane may produce a dose-dependent increase in cerebrospinal fluid pressure when administered to patients with space occupying lesions. In patients with coronary artery disease marked increases in pulse rate, mean arterial pressure and levels of epinephrine and norepinephrine are associated with rapid increase in desflurane concentrations. Desflurane should not be the sole anaesthetic agent for induction in patients at risk of coronary artery disease or when increases in heart rate or blood pressure are undesirable. After rapid increase in concentration of desflurane an increase in heart rate and blood pressure may not represent inadequate anaesthesia. Increases in heart rate and blood pressure without a rapid increase in desflurane concentration may be interpreted as light anaesthesia. Supportive analgesia should be administered at the end of the procedure or early in the post-anaesthesia care unit. Safety of desflurane has not been established for use in obstetric procedures. Desflurane is a uterine relaxant and reduces uterine-placental blood-flow. Desflurane is not indicated for use during pregnancy and lactation. **Contraindications**: Not to be used if general anaesthesia is contraindicated, known sensitivity to halogenated agents, or known or genetic susceptibility to malignant hyperthermia. Not for use in patients undergoing dental procedures outside a hospital or day care unit. Not for use in patients with liver dysfunction, jaundice, unexplained fever, leukocytosis or eosinophilia after previous halogenated anaesthetic administration. Not for use for induction in patients undergoing CABG. Not for use as an induction agent in paediatrics. **Interactions:** MAC for desflurane is reduced by concomitant nitrous oxide administration. Muscle relaxants are potentiated by desflurane. Increasing doses of fentanyl show a marked reduction in MAC. Midazolam showed a small reduction in MAC. **Overdose**: In the event of overdose or what may appear to be overdose, discontinue or minimize exposure to desflurane, establish an airway and initiate assisted or controlled ventilation with 100% oxygen, support and maintain adequate haemodynamics. **Legal category:** POM **Marketing Authorisation Number and Holder:** PA 2299/023/001 – Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands **Date of preparation:** June 2020. Further information available upon request.