SYNOPSIS

Sponsor/Company Orion Corporation Orion Pharma	Individual Study Table referring to a specific Part of the dossier Volume: Page	(for National Regulatory Authority use only)
Finished product: *dexdor*®		
Active ingredient: Dexmedetomidine		
Study code: 3005021		
Study title: A multinational, observational study to investigate the use of dexmedetomidine (*dexdor*®) in clinical practice		
Development phase: IV		
Objectives: The objective of the study is to investigate the use of Dexdor in clinical practice.		
Study sites: Hospitals from 4 different geographical regions in the European Union (EU) will be selected into the study. At least one country will be selected from each region and at least 2 suitable hospitals will be selected from each country to participate in this study as study sites (sites). The total number of enrolled sites will be approximately 15. The selection of hospitals as sites will be based on the sales of Dexdor and other suitability criteria, including the availability of adult and paediatric intensive care patients as assessed by formal site feasibility. The hospital sales from a minimum of 6 months after the Dexdor launch in a given country will be used to determine which hospitals should be considered for the study. It is assumed that the hospitals with the highest volumes of Dexdor use will provide the largest number of Dexdor patients and potentially the widest use of the drug. However it is also recognised that not all hospitals who meet these criteria will be suitable for the study and some may not be representative of the use patterns in the majority of other hospitals. Therefore, an initial site feasibility survey which will include a review of Dexdor usage and site set-up will be administered to the identified hospitals to assess the suitability of potential study sites as part of the formal site feasibility process. In addition, to achieve balance and aid interpretation, at least 1 enrolled site from each country will be a non-teaching hospital where possible. Furthermore, a random approach may also be used when selecting which of the suitable hospitals to approach or enrol.		
Methodology: This is a multinational, observational, retrospective drug utilisation study. All patients, both adults and children, receiving Dexdor in participating sites will have pre-defined data elements collected retrospectively from the patient medical records. The data collected will be anonymised at the source.		
Criteria for inclusion and exclusion: Countries and sites will be selected according to pre-specified suitability criteria as part of a formal feasibility process. All patients who were treated with Dexdor at the selected sites during the eligibility period (approximately 12-24 months post site initiation) for enrolment will be eligible for the study unless they were participating in a clinical trial involving dexmedetomidine at the time of Dexdor administration.		
Data collection: Predefined list of variables to address study objectives will be abstracted retrospectively from the medical records		
Investigational product, dose and mode of administration: None.		
Sample size and duration of study: The target sample size is 2000 patients. If the sample size is not reached within 2 years of starting data collection at the first site, the steering committee and the sponsor in consultation with the competent authorities, will review the data generated while the study is being conducted and, if patient accumulation at 2 years is significantly less than expected, will consider whether the objectives of the study have already been met and whether it is considered necessary to continue the study. Data collection is estimated to start approximately 1 year after the first launch in the EU to ensure that there is a		

reasonable amount of Dexdor usage to collect sufficient data for the study. Data collection at each site is planned to continue for a minimum of 1 year. This eligibility period may be extended if the required patient accrual is not achieved in this period, or shortened if maximum recruitment at the site is achieved sooner – an individual site may not contribute more than 300 patients to avoid undue influence on the overall study result.
Variables: • Site characteristics and background information on the use of dexmedetomidine (to be collected once per site, at the beginning of the study): o Country o Name of the hospital and departments using dexmedetomidine o Estimated date (month, year) of the first use of dexmedetomidine o Estimated number of patients treated with dexmedetomidine within the previous 12 months • Patient characteristics o Age and sex o Month and year of Dexdor administration o Primary indication for the use of Dexdor o Location of the use of Dexdor: hospital department o Dexdor dose administered o Route of dexdor administration o Duration of infusion of Dexdor o Therapeutic effectiveness of Dexdor o Relevant concomitant medications during the Dexdor treatment period
Evaluation and statistical methods: The aim is to investigate Dexdor use and evaluate observed compliance with the current marketing license. The use of Dexdor will be summarised into categories of patient details (age, sex), indication for and therapeutic effectiveness of Dexdor treatment, relevant concomitant medications, hospital department, site/country and time period. The characteristics of patients and Dexdor use by indication and hospital department will be summarised and compared.
Adverse event reporting: As per Guideline on Good Pharmacovigilance Practices (GVP), Module VI – Management and reporting of adverse reactions to medicinal products (2 July 2012), adverse reaction reporting is not required for non-interventional study designs based on secondary use of data. Reports of adverse events/ reactions should only be summarised in the study report, where applicable.