sRMP

Dexmedetomidine "Mylan

DE/H/5280/001/DC

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Not applicable.

VI.2.2 Summary of treatment benefits

Dexmedetomidine is used to provide sedation (a state of calm, drowsiness or sleep) for adult patients in hospital intensive care settings. It is administered to you by a doctor or nurse, who will decide on a suitable dose for you. The amount of dexmedetomidine depends on your age, size, general condition of health, the level of sedation needed and how you respond to the medicine. Your doctor may change your dose if needed and will monitor your heart and blood pressure during the treatment. Dexmedetomidine is diluted and it is given to you as an infusion (drip) into your veins. In clinical trials, dexmedetomidine has proven to be as effective as other drugs such as midazolam and propofol with regards to the time in target sedation range and it showed reduced duration of mechanical ventilation and reduced the time to extubation compared to these drugs. Compared to both propofol and midazolam, patients were more easily roused, more cooperative and better able to communicate whether or not they had pain. In addition, dexmedetomidine does not depress normal breathing and can therefore be safely given to patients without a breathing tube.

VI.2.3 Unknowns relating to treatment benefits

Pregnancy: If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Dexmedetomidine Mylan should not be used during pregnancy or breast-feeding unless clearly necessary.

Dexmedetomidine Mylan use in patients with chronic neurological disorders: dexmedetomidine should be used cautiously in patients who have a neurological disorder (for instance head or spinal cord injury or stroke).

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Cardiovascular events (high or low blood pressure and slow heart rate)	Symptoms such as slow heart rate have been known to occur very frequently with the use of dexmedetomidine	Yes, by monitoring for early symptoms. Tell your doctor immediately, if you notice any of these symptoms while being treated with dexmedetomidine.
High blood sugar (Hyperglycaemia)	High blood sugar levels have been known to occur commonly with the use of dexmedetomidine.	Yes, by monitoring for early symptoms. Tell your doctor immediately, if you notice any symptoms while being treated with dexmedetomidine.
Symptoms after stopping dexmedetomidine (Withdrawal syndrome)	Alpha-2 agonists (the group of medicines dexmedetomidine belongs to) have sometimes been associated with symptoms such as agitation or increase in blood pressure shortly after stopping dexmedetomidine.	Yes, by monitoring for early symptoms. Tell your doctor immediately, if you notice any symptoms while being treated with dexmedetomidine.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Heart disorders such as heart artery disease, heart rhythm disorders, abnormality in the heart's electrical system possibly leading to very fast and dangerous heart rhythm or abrupt cessation of normal circulation of the	Patients treated with dexmedetomidine may be at an increased risk of developing symptoms such as chest pain or heart attack or slow or fast heart rate. Tell your doctor immediately, if you notice any such symptoms while being treated with dexmedetomidine.

Risk	**What is known (Including reason why it is considered a potential risk)**
blood due to failure of the heart to contract effectively [Cardiac events (ischaemic heart disease, atrioventricular block, torsade de pointes/QT prolongation and cardiac arrest)]	
Use of higher dosage than indicated (Overdose)	If you are given too much dexmedetomidine, your blood pressure may drop, your heartbeat may slow down and you may feel drowsy. Tell your doctor immediately, if you notice any such symptoms while being treated with dexmedetomidine. Your doctor will know how to treat you based on your condition.
Prescription of medication for a medical purpose not in accordance with the product labelling (Off-label use)	Dexmedetomidine belongs to the medicine group called sedatives and it is used to provide sedation (a state of calm, drowsiness or sleep) for adult patients in hospital intensive care settings. If you have any further questions on the use of this medicine, ask your doctor.
Depressed function of the respiratory system (Respiratory depression)	Some patients may experience change in breathing pattern or stopping breathing while being treated with dexmedetomidine. Tell your doctor immediately, if you notice any symptoms while being treated with dexmedetomidine.
Tachypnoeic potential	Some patients may experience shortness of breath while being treated with dexmedetomidine. Tell your doctor immediately, if you notice any symptoms while being treated with dexmedetomidine.
Low blood sugar (Hypoglycaemia)	Patients treated with dexmedetomidine may experience low blood sugar levels. Tell your doctor

Risk	What is known (Including reason why it is considered a potential risk)
	immediately, if you notice any symptoms while being treated with dexmedetomidine.
Cortisol suppression	Patients treated with dexmedetomidine may be at an increased risk of developing decreased secretion of cortisol. Cortisol is involved in regulation of several metabolic processes in the body, e.g. regulation of blood sugar levels, and in function of body defence mechanisms (immune system). Medications with a certain chemical structure also included in the group of dexmedetomidine have shown to play a role in the development of this event. However, the evidence of the role of dexmedetomidine in these reactions is currently sparse. Tell your doctor immediately, if you notice any symptoms while being treated with dexmedetomidine.
Convulsions	Dexmedetomidine is not suspected to cause convulsions as such. However, unlike other sedatives, it lacks the anticonvulsant action other sedatives have so will not suppress underlying seizure activity. Tell your doctor immediately, if you notice any symptoms while being treated with dexmedetomidine.
Hypothermia	Medication with the same mechanism of action as dexmedetomidine have been shown to reduce body temperature. Tell your doctor immediately, if you notice any symptoms while being treated with dexmedetomidine.

Missing information

Risk	What is known
Pregnancy	If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Dexmedetomidine should not be used during pregnancy or breast-feeding unless clearly necessary.
Chronic conditions of the nervous system (Chronic neurological conditions)	The data on the usage of dexmedetomidine in patients with chronic conditions of the nervous system are limited. As dexmedetomidine may reduce blood flow in the brain, caution should be used when administering dexmedetomidine to this group of patients. Tell your doctor immediately, if you notice any symptoms while being treated with dexmedetomidine.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet. The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures

VI.2.6 Planned post authorisation development plan

No studies planned.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable.