

DEXMEDETOMIDINE EVER PHARMA

Dexmedetomidine hydrochloride

Dexmedetomidine is a selective α_2 adrenoceptor agonist originally developed for light to moderate sedation in adult intensive care unit (ICU) patients.

DEXMEDETOMIDINE EVER PHARMA is indicated for sedation of initially intubated patients during treatment in an intensive care setting, and for sedation of non-intubated patients prior to and/or during surgical and other procedures (procedural sedation).

200 mcg **2mL (amp)**

400 mcg **4mL (vial)**

1000 mcg **10mL (vial)**

Available as either ampoules, or larger vial presentations – for additional convenience

New 1000mcg vial – useful when preparing larger doses for longer sedation periods



DEXMEDETOMIDINE EVER PHARMA

Dexmedetomidine hydrochloride

Active Ingredient	Dexmedetomidine hydrochloride
Excipients	Sodium chloride (Each ml of concentrate contains less than 1 mmol (approximately 3.5mg sodium), Water for injections
Immediate Container	2ml Type I colourless glass ampoules 5 or 10ml Type I colourless glass vials (with filling volumes of 4 and 10ml), bromobutyl rubber closure with fluoropolymer coating
Closure	Bromobutyl rubber closure with fluoropolymer coating
Strengths	Each 1ml of DEXMEDETOMIDINE EVER PHARMA contains 118 microgram of dexmedetomidine hydrochloride (equivalent to 100 microgram dexmedetomidine base) and 9mg of sodium chloride in water for injections. The solution is preservative-free and contains no additives or chemical stabilisers
Pack size	Presented in 4mL and 10ml vials and 2ml ampoules. Must be diluted prior to use: 200 microgram/2ml concentrated injection contains 200 microgram of dexmedetomidine and is available as glass ampoules in pack sizes of 5 x 2ml 400 microgram/4ml concentrated injection contains 400 microgram of dexmedetomidine and is available as glass vials in pack sizes of 1 x 4ml 1000 microgram/10ml concentrated injection contains 1000 microgram of dexmedetomidine and is available as glass vials in pack sizes of 1 x 10ml Not all pack sizes may be marketed
Indications	ICU Sedation: For sedation of initially intubated patients during treatment in an intensive care setting. The use of DEXMEDETOMIDINE EVER PHARMA by continuous infusion in these patients should not exceed 24 hours Procedural Sedation: For sedation of non-intubated patients prior to and/or during surgical and other procedures
Stability	
Unopened	2 years, Store below 25°C
After 1st Opening	Once the vial has been opened, the product must be used immediately
Solution for Infusion	Chemical and physical stability of the diluted infusion (Infusion Solution Stability) has been demonstrated for 48 hours at 25°C and at refrigerated conditions (2°C – 8°C). From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to the use are the responsibility of the user and would not normally be longer than 24 hours at 2° to 8°C, unless dilution has taken place in controlled and validated aseptic conditions

