CLAIMS

1. Parenteral formulation of esmolol hydrochloride for use in the treatment of a patient suffering from tachycardia comprising a ready-to-use i.v. solution of esmolol hydrochloride at a concentration of 20-100 mg/ml, which is reconstituted from a lyophilized powder consisting of ~~pure~~ at least 95% purity esmolol hydrochloride, ~~wherein said powder is reconstituted to obtain a ready-to-use i.v. solution of esmolol hydrochloride at a concentration of 20-100 mg/mL~~ and wherein said i.v. solvent devoid of alcohol selected from the group consisting of water for injection (WFI), glucose solution, glucose and Ringer solution, glucose and saline solution, saline solution, Ringer Lactate solution or Ringer Lactate and saline solution, and said i.v. solution is directly administered to the patient.

~~2. Formulation according to claim 1, wherein said powder is reconstituted in an i.v. solvent devoid of alcohol, selected from the group consisting of water for injection (WFI), glucose solution, glucose and Ringer solution, glucose and saline solution, saline solution, Ringer Lactate solution or Ringer Lactate and saline solution.~~

~~3.~~2. Formulation according to claim~~s~~ 1 ~~or 4~~, wherein said i.v. solution has a pH of 4.5 to 5.0.

~~4.~~3. Formulation according to ~~any of~~ claim~~s~~ 1 ~~to~~ or ~~3~~2, wherein said esmolol hydrochloride concentration is at least 50 mg/mL.

~~5.~~4. Formulation according to any of claims 1 to ~~4~~3, wherein said i.v. solution is administered as continuous infusion.

~~6.~~5. Formulation according to any of claims 1 to ~~5~~4, wherein said i.v. solution is administered as maintenance infusion at a dose of at least 25 µg/kg/min, optionally following an initial infusion at a dose of at least 300 µg/kg/min.

~~7.~~6. Formulation according to any of claims 1 to ~~6~~5, wherein said i.v. solution is local tissue tolerant at the infusion site, preventing local venous irritation or skin necrosis at the infusion site.

~~8.~~7. Formulation according to any of claims 1 to ~~7~~6, wherein said patient is

a. suffering from any of acute tachycardia selected from supraventricular tachycardia, ventricular tachycardia or hypertension and non-compensatory sinus

tachycardia, atrial fibrillation, atrial flutter in perioperative, postoperative, or other circumstances where short-term control of the ventricular rate is desirable, or
b. in need of blood pressure lowering during aortic dissection or for controlled hypotension to avoid blood loss in ear/ nose/ throat surgery or for diagnostic purposes.

~~9.~~8. Formulation according to any of claims 1 to ~~8~~7, wherein said patient is having cardiac decompensation ~~and~~/or hyperhydrat~~a~~tation ~~and~~/or renal decompensation ~~and~~/or hypernatremia ~~and~~ /or hyperchloramic acidosis ~~and/or hyperhydratation~~.

9. Formulation according to any of claim 1 to 7, wherein said patient is having cardiac decompensation and hyperhydration and renal decompensation and hypernatremia and hyperchloramic acidosis.

10. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation and hyperhydration or renal decompensation or hypernatremia or hyperchloramic acidosis.

11. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation and hyperhydration and renal decompensation or hypernatremia or hyperchloramic acidosis.

12. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation and hyperhydration and renal decompensation and hypernatremia or hyperchloramic acidosis.

13. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation or hyperhydration and renal decompensation or hypernatremia or hyperchloramic acidosis.

14. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation or hyperhydration and renal decompensation and hypernatremia or hyperchloramic acidosis.

15. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation or hyperhydration and renal decompensation and hypernatremia and hyperchloramic acidosis.

16. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation or hyperhydration or renal decompensation and hypernatremia or hyperchloramic acidosis.

17. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation or hyperhydration or renal decompensation and hypernatremia and hyperchloramic acidosis.

18. Formulation according to any of claims 1 to 7, wherein said patient is having cardiac decompensation or hyperhydration or renal decompensation or hypernatremia and hyperchloramic acidosis.

~~10~~19. Method of producing a ready-to-use i.v. solution of esmolol hydrochloride by reconstituting a lyophilized powder consisting of ~~pure~~ at least 95% purity esmolol hydrochloride with a solvent, wherein said solvent is an i.v. solvent devoid of alcohol or a buffer excipient, in an amount necessary to obtain a ready-to-use i.v. solution at a concentration of 20-100 mg/mL.

~~11~~20. Ready-to-use i.v. solution containing a parenteral formulation of 20-100 mg/mL reconstituted lyophilized esmolol hydrochloride at a concentration of 20-100 mg/mL obtained from ~~pure~~ at least 95% purity lyophilized esmolol hydrochloride in an infusion device.

~~12~~21. Ready-to-use i.v. solution comprising a parenteral formulation of 20-100 mg/mL ~~pure~~ at least 95% purity reconstituted lyophilized esmolol hydrochloride at a concentration of 20-100 mg/mL obtained from ~~pure~~ at least 95% purity lyophilized esmolol hydrochloride, WFI and/or saline solution, devoid of any alcohol or buffer excipients.

~~13~~22. Ready-to-use i.v. solution consisting of ~~pure~~ at least 95% purity reconstituted lyophilized esmolol hydrochloride at a concentration of 20-100 mg/mL obtained from ~~pure~~ at least 95% purity lyophilized esmolol hydrochloride, WFI and optionally saline.

~~14. Kit for preparing a parenteral formulation according to claim 11 to 13, comprising the components~~

~~a) a lyophilized powder consisting of pure esmolol hydrochloride, and~~

~~b) WFI or saline solution, and optionally~~

~~c) an infusion device suitable for i.v. administration.~~

~~15. Kit according to claim 14, wherein 2500 mg of the powder is contained in a 50 mL vial.~~

~~16~~23. Use of the parenteral formulation of esmolol hydrochloride as defined in any of claims 1 to ~~9~~ 18 in the manufacture of a medicament for the treatment of tachycardia.