



From development to market.

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Certificate of Translation Accuracy

Date: 27 March 2023

Arriello sro hereby certifies that the linguists who worked on this translation specialize in pharmaceutical and medical translations and is competent in Sweden and English to render a true and correct translation. **Arriello sro** further declares to have followed the necessary quality assurance steps in compliance with industry standards to perform the translation and, to the best of our knowledge, the translations are true and correct English versions of each original document.

(Marcaïne Spinal 0.5%)

English documents:

Bupi-Sp_inj_SE_S_5mg_ml_v1_EN dated 2018.01.31

is the translation of Sweden document:

Bupi-Sp_inj_SE_S_5mg_ml_v2 dated 2023.01.13, except the changes detailed in Table 1.

Table 1

Bupi-Sp_inj_SE_S_5mg_ml_v1_EN dated 2018.01.31	Bupi-Sp_inj_SE_S_5mg_ml_v2 dated 2023.01.13 (Swedish text)	Translation of the changes into English
4.4 Special warnings and precautions for use *** ---	4.4 Varningar och försiktighetsmått *** Detta läkemedel innehåller mindre än 1 mmol natrium (23 mg) per milliliter, d.v.s. är näst intill” natriumfritt”.	4.4 Special warnings and precautions for use *** This medicine contains less than 1 mmol (23 mg) of sodium per millilitre, i.e. it is almost “sodium free”.
6.3 Shelf life Glass ampoules: 3 years. ---	6.3 Hållbarhet Glasampuller: 3 år <u>Överblivet innehåll kasseras.</u>	6.3 Shelf life Glass ampoules: 3 years. Leftover content is to be discarded.

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The solution should be used immediately after opening the pack.	Lösningen ska förbrukas genast efter att förpackningen brutits.	
31 January 2018	31 January 2018 2023-01-13	2023-01-13

(Marcaine 0.5% Spinal Heavy)

English documents:

Bupi-SpH_inj_SE_S_5mg_ml_v1_EN dated 2018.01.31

is the translation of Sweden document:

Bupi-SpH_inj_SE_S_5mg_ml_v2 dated 2023.01.13, except the changes detailed in Table 2.

Table 2

Bupi-SpH_inj_SE_S_5mg_ml_v1_EN dated 2018.01.31	Bupi-SpH_inj_SE_S_5mg_ml_v2 dated 2023.01.18 (Swedish text)	Translation of the changes into English
4.4 Special warnings and precautions for use *** ---	4.4 Varningar och försiktighetsmått *** Detta läkemedel innehåller mindre än 1 mmol natrium (23 mg) per milliliter, d.v.s. är näst intill” natriumfritt”.	4.4 Special warnings and precautions for use *** This medicine contains less than 1 mmol (23 mg) of sodium per millilitre, i.e. it is almost “sodium free”.
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31 January 2018	31 January 2018 2023-01-18	2023-01-13

Full Name: Raluca Sava

Signature:

A handwritten signature in blue ink, appearing to be 'Raluca Sava', written in a cursive style.

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