

## Public assessment summary report

<b>Name of the Finished Pharmaceutical Product</b>	PASURTA (erenumab) 140 mg/mL Solution for injection in a prefilled syringe
<b>Manufacturer of the Finished Product</b>	Biofarm Sp. z o.o. Poland 13 Wałbrzyska St. 60-198 Poznań – Poland
<b>Active Pharmaceutical Ingredient (API)</b>	Erenumab

### 1. Introduction

Based on review of quality, safety and efficacy data through the abbreviated approval procedure, the authority granted a marketing authorization for PASURTA (erenumab) 140 mg/mL solution for injection in a prefilled syringe.

Pasurta is anti-Calcitonin Gene-Related Peptide Receptor (anti-CGRPR) monoclonal antibody and indicated for prophylaxis of migraine in adults.

### 2. Assessment of quality

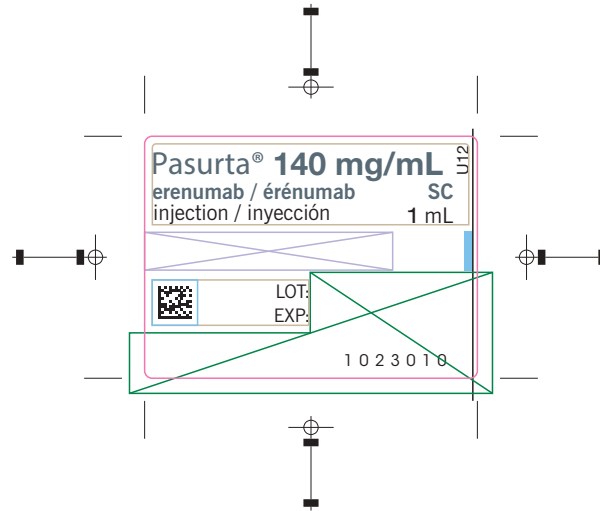
GMP compliance of the API manufacture was demonstrated by document review. The necessary waiver for cGMP of the finished pharmaceutical product manufacturer has been carried out. Marketing authorization was granted by the stringent regulatory authority (SRA) and appropriate verification of marketing authorization was performed.

#### ***Stability testing:***

It is confirmed that the finished product stability studies were conducted in the container closure system proposed for the marketing of the product in accordance with the current medicine registration guideline of Ethiopia.

### 3. Conclusion

Based on assessment of administrative and technical document, it is considered that the benefit–risk profile of PASURTA (erenumab) 140 mg/mL Solution for injection in a prefilled syringe is acceptable for the treatment indicated above.

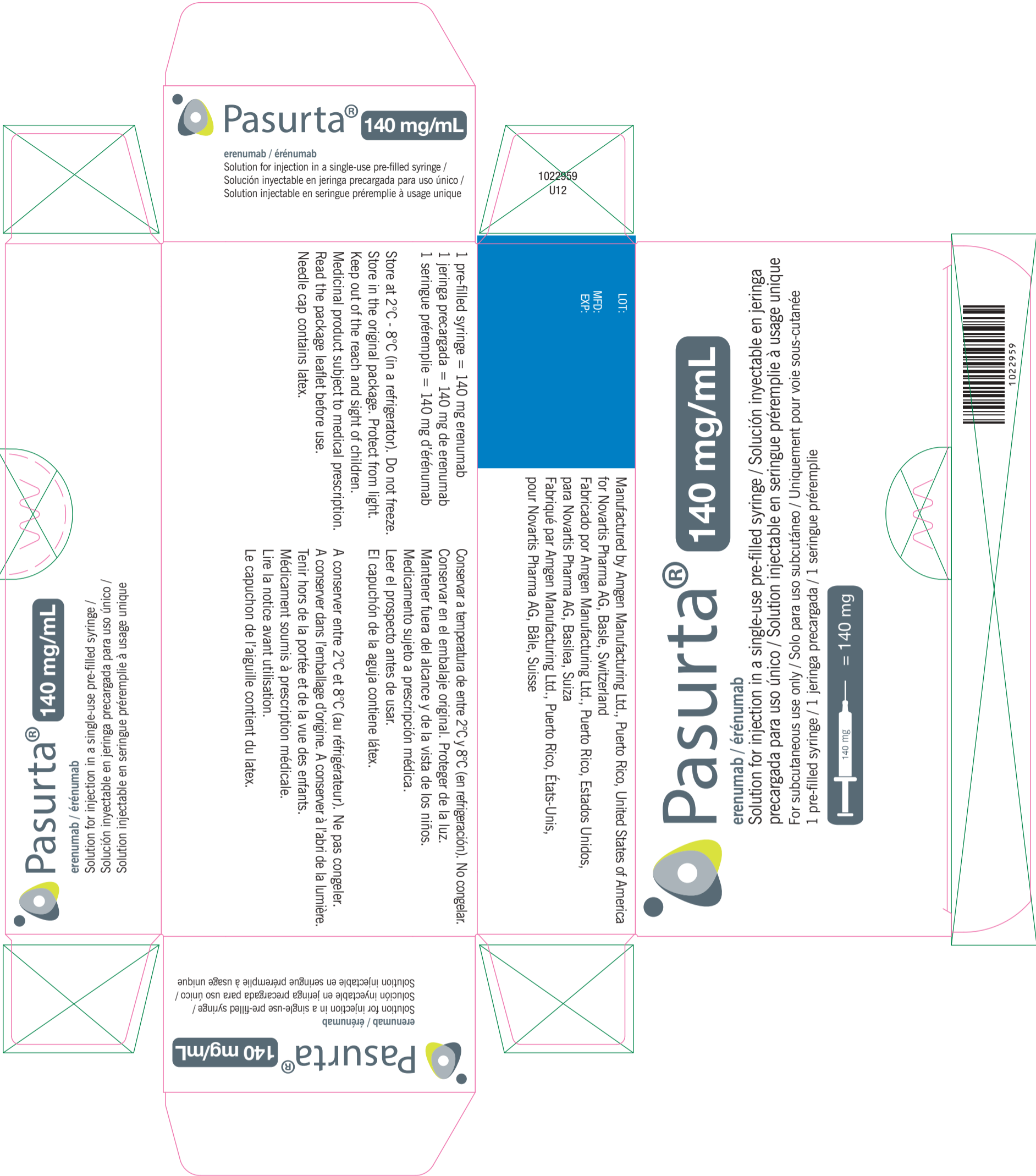


				August Faller Artwork Solutions GmbH Fabrik Sonntag 4b D-79183 Waldkirch www.august-faller.com	
Live Text:	<input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No / <input type="checkbox"/> Both	Production Site:	Netherlands, TPO, Amgen, Breda		
WO:	1866922	ACC:	Alii Md Ahmed		
Comp. Description:	Label_Aimovig (PASURTA)_LISY_PFS_140MG 1ML_U12	Printing Colours:	Black Pantone 7545 C		
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Comp. No. Old:	n.a.				
Format/Dimension:	44.0 x 32.0 mm				
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Proof No.:	3	13.01.2020	M. Zimmermann		

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Live Text:	<input type="checkbox"/> Yes / <input type="checkbox"/> No / <input checked="" type="checkbox"/> Both	Production Site: Netherlands, TPO, Amgen, Breda
WO:	1866926	ACC: Ali Md Ahmed
Comp. Description:	Folding Box_AMG334 LISY 140MG GLW 1ML (X) B0 U12 (PASURTA)	Printing Colours: Black Pantone 285 C Pantone 381 C Pantone 7545 C
Comp. No. New:	1022959 U12	
Comp. No. Old:	n.a.	
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Proof No.: 3	10.01.2020 M. Zimmermann	

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