

## To Whom It May Concern

Basel, 27 January 2025

### **POLIVY® 30 mg powder for concentrate for solution for infusion** **POLIVY® 140 mg powder for concentrate for solution for infusion**

Dear Sir/Madam,

nominal amount (without overfill) per 1 vial **Polivy 30 mg** is:

<b>Ingredients</b>	<b>Quantity/Vial</b>
Polatuzumab vedotin	30 mg
Succinic acid	1.77 mg
Sodium hydroxide (for pH-adjustment)	0.82 mg
Sucrose	62 mg
Polysorbate 20 (E 432)	1.8 mg

The nominal amount (without overfill) per 1 vial **Polivy 140 mg** is:

<b>Ingredients</b>	<b>Quantity/Vial</b>
Polatuzumab vedotin	140 mg
Succinic acid	8.27 mg
Sodium hydroxide (for pH-adjustment)	3.80 mg
Sucrose	288 mg
Polysorbate 20 (E 432)	8.4 mg

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Registergericht:  
Freiburg HRB 717155

Geschäftsführung:  
Dr. Julia Wagle  
USt-IdNr.: DE314809599

The density of Polivy 30 mg and 140 mg vial (lyophilized powder for concentrate for solution for infusion) reconstituted with WFI is 1.02 g/mL at room temperature.

On behalf of Roche Registration GmbH,

ppa.



Dr. Holger Raviol

Pharma Technical Regulatory

ppa.



Dr. Andreas Emmendoerffer

Pharma Technical Regulatory

**Roche Registration GmbH**

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