

TO WHOM IT MAY CONCERN

Basel , 20 October 2023

Kadcyla 100 mg powder for concentrate for solution for infusion.
Kadcyla 160 mg powder for concentrate for solution for infusion.

The nominal weight (without overfill) per vial Kadcyla 100 mg is:
Trastuzumab emtansine (drug substance): 106 mg
Excipients: 327,8 mg **Total: 433,8 mg**

The nominal weight (without overfill) per vial Kadcyla 160 mg is:
Trastuzumab emtansine (drug substance): 171 mg
Excipients: 529,7 mg **Total: 700,7 mg**

The density of Kadcyla 20 mg/ml reconstituted in sterile water is 1.03 g/ml at room temperature

On behalf of Roche Registration GmbH,

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