Erba Lachema s.r.o.

ADVISORY NOTICE

MISTAKE IN PACK INSERT

Cat. No.	Pack Name	Lot
XSYS0056	HbA1c CON H	2010114

Dear customer,

We apologize for a mistake in the pack inserts of above stated products. In the table of attested values were stated a wrong Lot numbers.

ASSIGNED VALUES

Target values according to IFCC (mmol/mol):

	Lot No.	Expiry Date		Targer value (mmol/mol)	Range (mmol/mol)	1 SD (mmol/mol)
HbA1c Control High	29656	11/2021	3-component system	95.2	76.2 – 114	6.30
			2-component system	92.7	74.2 – 111	6.13

Target values according to DCCT/NGSP (%):

	Lot No.	Expiry Date		Targer value (%)	Range (%)	1 SD (%)
HbA1c Control High	29656	11/2021	3-component system	10.9	9.12 – 12.6	0.58
			2-component system	10.6	8.94 – 12.3	0.56

The correct Lot numbers are mentioned in the headline of the pack inserts and on the labels.

HbA1c CONTROL

Lot: 2010114

Cat. No.	Pack Name	Packaging (Content)
XSYS0056	HBA1C CON H	1 x 0.25 ml

Since the next batch we decided to remove the information about Lot and expiry from the table of attested values and mention this information in the headline only.

Best regards,

Erba Lachema s.r.o.
Karásek 2219/1d, 621 00 Brno
DIČ: CZ26918846 -22-

Erba Lachema s.r.o.
Technical Product Management

Brno, 16. 2. 2021