Published by Ministry of Health, Labour and Welfare Translated by Pharmaceuticals and Medical Devices Agency





This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

## **Revision of Precautions**

Insulin lispro (genetical recombination) (vial preparations)
Insulin lispro (genetical recombination) [insulin lispro biosimilar 1] (vial preparations)

May 19, 2020

## Therapeutic category

Hormones-miscellaneous

## Non-proprietary name

Insulin lispro (genetical recombination), insulin lispro (genetical recombination) [insulin lispro biosimilar 1]

## Safety measure

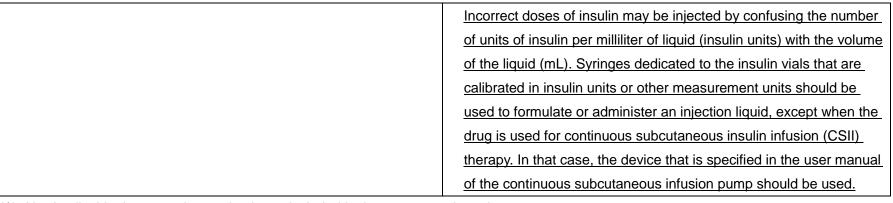
Precautions should be revised in the package insert.

**Pharmaceuticals and Medical Devices Agency** 

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions):

Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS	8. IMPORTANT PRECAUTIONS
(N/A)	By repeated injection into the same spot, cutaneous amyloidosis or
	lipodystrophy may occur in the injection site. Injection sites should
	be examined periodically and patients should be instructed as
	follows:
	•This drug should be injected at least 2 to 3 cm apart from the
	previous injection site.
	• If any masses and indurations that formed in the injection site are
	noted, injection into the affected area should be avoided.
	Injection of this drug into areas where cutaneous amyloidosis or
	lipodystrophy developed may impede the absorption of this drug
	and result in poor glycemic control. If poor glycemic control is
	recognized, the injection site should be examined for mass or
	induration and appropriate measures should be taken such as
	changing the injection site as well as dose adjustment. Cases of
	hypoglycemia have been reported that occurred after the injection
	site was changed, and insulin preparation was injected into an
	unaffected area in doses excessively increased in association with
	the poor glycemic control.



N/A: Not Applicable, because the section is not included in the current package insert.