

Summary of Investigation Results

Insulin aspart (genetical recombination)

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Insulin aspart (genetical recombination)	Fiasp Injection 100 U/mL (Novo Nordisk Pharma Ltd.)
Japanese market launch	February 2020	
Indications	Diabetes mellitus for which insulin therapy is indicated	
Summary of revisions	Precautions for occlusion in a portable insulin pump associated with exposure to high temperature exceeding 37 degrees C. should be added to the 8. IMPORTANT PRECAUTIONS section.	
Investigation results and background of the revision	Cases of serious hyperglycaemia and diabetic ketoacidosis after administration of insulin aspart (genetical recombination) using a portable insulin pump have been reported. These events were considered to be due to a failure to deliver the insulin appropriately because of pump occlusion associated with gelling of the insulin as a result of using the insulin pump at high temperature. Based on the above, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	