

Summary of Investigation Results

Inclisiran sodium

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Inclisiran sodium	Leqvio for s.c. injection syringe 300 mg (Novartis Pharma K.K.)
Japanese market launch	November 2023	
Indications	Familial hypercholesterolemia, hypercholesterolemia For use only in patients who met all of the following: • High risk of developing cardiovascular events • Patients who have not sufficiently responded to an HMG-CoA reductase inhibitor or in whom treatment with HMG-CoA reductase inhibitors is not suitable	
Summary of revisions	"Hypersensitivity" should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving hypersensitivity were evaluated. Cases in which a causal relationship between inclisiran sodium and hypersensitivity was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	
Reference: Number of cases* involving hypersensitivity* ¹ reported in Japan and overseas	Japan	Overseas* ²
	A total of 2 cases have been reported to date (including 0 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.	A total of 28 cases have been reported to date (including 16 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.

*1: Cases corresponding to MedDRA v29.0 SMQ "Hypersensitivity (broad)" among those collected in PMDA's safety database for drugs

*2: Among serious cases with high clinical significance equivalent to CTCAE Grade 3 or higher, cases excluding those in which the causal relationship between the drug and the event was ruled out by the marketing authorization holder

*: Cases collected in PMDA's safety database for drugs.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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