Summary of Investigation Results

Pabinafusp alfa (genetical recombination)

July 17, 2024

Non-proprietary name

Pabinafusp alfa (genetical recombination)

Brand name (marketing authorization holder)

Izcargo for I.V. infusion 10 mg (JCR Pharmaceuticals Co., Ltd.)

Japanese market launch

May 2021

Indications

Mucopolysaccharidosis II

Summary of revisions

The 9.5 Pregnant Women section of 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS should be deleted.

Investigation results and background of the revision

The results of the reproductive and developmental toxicity study of pabinafusp alfa (genetical recombination), which was conducted post-marketing, were evaluated. In addition to the fact that the reproductive and developmental toxicity study was conducted, as a result of consultation with expert advisors, in which no special concerns were raised, the MHLW/PMDA concluded that revision of PRECAUTIONS was appropriate in accordance with the following: No.37 of the administrative notice by the Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated January 17, 2019, “Questions and Answers (Qs and As) Regarding Descriptions in the Package Inserts, etc. of Prescription Drugs” (last amended on February 17, 2023).

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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.

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).

Pharmaceuticals and Medical Devices Agency

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