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.

Summary of Investigation Results

Purified pineapple stem juice

August 27, 2024

Non-proprietary name

Purified pineapple stem juice

Brand name (marketing authorization holder)

NexoBrid gel 5 g (Kaken Pharmaceutical Co., Ltd.)

Japanese market launch

August 2023

Indications

Removal of necrotic tissue of deep dermal burn or deep burn

Summary of revisions

1. The “Patients with wound such as decompression incision and laceration” subsection should be added to the 9.1 Patients with Complication or History of Diseases, etc. section, which should be newly added to the 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section. A precautionary statement concerning haemorrhage due to contact between the wound area and this drug should be included in the subsection.
2. “Application site haemorrhage” 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 haemorrhage were evaluated. Cases for which a causal relationship between the adverse reaction related to haemorrhage and purified pineapple stem juice was reasonably possible have been reported. As a result of consultation with expert advisors

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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*† and patient mortalities involving haemorrhage reported in Japan

A total of 4 cases have been reported to date. (A causal relationship between the drug and event was reasonably possible for these cases.)

One instance of patient mortality has been reported to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

* Cases collected in the PMDA's database for adverse drug reactions, etc. reports

† Cases with an adverse reaction name (PT) containing “haemorrhage”

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).

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