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

Levonorgestrel (preparations indicated for emergency contraception)

February 3, 2022

Non-proprietary name

Levonorgestrel

Brand name (Marketing authorization holder)

Norlevo Tablet 1.5 mg (Aska Pharmaceutical Co., Ltd.), and the others

Indications

Emergency contraception

Summary of revisions

<New instructions>

1. From the Patients with Reproductive Potential section, examples of methods to confirm the absence of pregnancy (such as a pelvic examination and immunoassay-based diagnosis of pregnancy) should be deleted.
2. The cautionary statement in the Patients with Reproductive Potential section should be moved to the IMPORTANT PRECAUTIONS section.
3. The language concerning the foetal effects in the Pregnant Women section should be reinstated as risk information of other progestogen preparations and moved to the OTHER PRECAUTIONS section, which should be newly added.
4. Language should be added to the Pregnant Women section indicating that this drug is not effective in an existing pregnancy.
5. A statement should be added to the Pregnant Women section that it has been reported that there were no differences in the incidence of foetal malformation, miscarriage, or

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any other adverse pregnancy outcomes in pregnancies, despite use of this drug compared with pregnancies without such use.

<Old instructions>

1. From the Important Precautions section, examples of methods to confirm the absence of pregnancy (such as a pelvic examination and immunoassay-based diagnosis of pregnancy) should be deleted.
2. The language concerning the foetal effects in the Use during Pregnancy, Delivery or Lactation section should be reinstated as risk information of other progestogen preparations and moved to the Other Precautions section.
3. Language should be added to the Use during Pregnancy, Delivery or Lactation section indicating that this drug is not effective in an existing pregnancy.
4. A statement should be added to the Use during Pregnancy, Delivery or Lactation section that it has been reported that there were no differences in the incidence of foetal malformation, miscarriage, or any other adverse pregnancy outcomes in pregnancies, despite use of this drug compared with pregnancies without such use.

Investigation results and background of the revision

Considering the current description in the clinical practice guidelines regarding the methods to confirm the absence of pregnancy prior to administration of this drug for emergency contraception and regarding the foetal effects of this drug as well as search results of published literature, the necessity of revision of the package insert was discussed. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

Not applicable

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).