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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.*

# Revision of Precautions

## Levonorgestrel (preparations indicated for emergency contraception)

February 3, 2022

### **Therapeutic category**

Contraceptives

### **Non-proprietary name**

Levonorgestrel

### **Safety measure**

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p><b>Important Precautions</b></p> <p>Prior to administration of this drug, the absence of pregnancy should be <u>adequately confirmed through methods such as a pelvic examination and immunoassay-based diagnosis of pregnancy.</u> In addition, the current or past presence or absence of abnormal hepatic function and heart or renal diseases should be confirmed through an interview or other appropriate measures.</p> <p><b>Use during Pregnancy, Delivery or Lactation</b></p> <p>This drug should not be administered to pregnant women. <u>[If this drug is administered in the first or second trimester of pregnancy, external genital virilization in female fetuses or feminization of male fetuses may occur.]</u></p> <p>(N/A)</p>	<p><b>Important Precautions</b></p> <p>Prior to administration of this drug, the absence of pregnancy should be confirmed. In addition, the current and past presence or absence of abnormal hepatic function and heart or renal diseases should be confirmed through an interview or other appropriate measures.</p> <p><b>Use during Pregnancy, Delivery or Lactation</b></p> <p>This drug should not be administered to pregnant women. <u>[This drug is not effective in an existing pregnancy.]</u></p> <p><u>An observational study conducted overseas has reported that there were no differences in the incidence of foetal malformation, miscarriage, or any other adverse pregnancy outcomes in pregnancies, despite taking levonorgestrel as an emergency contraceptive compared with pregnancies without exposure to levonorgestrel.</u></p>

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(N/A)	<u>Other Precautions</u> <u>External genital abnormality has been reported in infants born to women who used other progestogen preparations, although not for the purpose of emergency contraception.</u>
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(References) Zhang,L.,et al.:Human Reproduction 2009;24(7):1605-1611

Huggins,G,R.,et al.:Fertility&Sterility 1990;54(4):559-573

N/A: Not Applicable. No corresponding language is included in the current package insert.

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>(N/A)</p> <p>Prior to administration of this drug, the current and past presence or absence of abnormal hepatic function and heart or renal</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>This drug is indicated for avoidance of pregnancy sought after sexual intercourse. For planned contraception, more effective contraceptive options such as oral contraceptives should be used whenever possible.</u></p> <p><u>Pregnancy may not be avoided following administration of this drug. Instructions on appropriate options for routine contraception should be given by the healthcare provider.</u></p> <p>Prior to administration of this drug, <u>the following should be confirmed:</u></p>

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diseases should be confirmed through an interview or other appropriate measures.

## 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

### 9.4 Patients with Reproductive Potential

This drug is indicated for avoidance of pregnancy sought after sexual intercourse. For planned contraception, more effective contraceptive options such as oral contraceptives should be used whenever possible.

Pregnancy may not be avoided following administration of this drug. Instructions on appropriate options for routine contraception should be given by the healthcare provider.

Prior to administration of this drug, the absence of pregnancy should be adequately confirmed through methods such as a pelvic examination and immunoassay-based diagnosis of pregnancy.

### 9.5 Pregnant Women

This drug should not be administered. If this drug is administered in the first or second trimester of pregnancy, external genital virilization in female fetuses or feminization of male fetuses may

. The person is not pregnant.

.The current and past presence or absence of abnormal hepatic function and heart or renal diseases through an interview or other appropriate measures.

## 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

(deleted)

### 9.5 Pregnant Women

This drug should not be administered. This drug is not effective in an existing pregnancy.

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<p><u>occur.</u></p> <p>(N/A)</p> <p>(N/A)</p>	<p><u>An observational study conducted overseas has reported that there were no differences in the incidence of foetal malformation, miscarriage, or any other adverse pregnancy outcomes in pregnancies, despite taking levonorgestrel as an emergency contraceptive compared with pregnancies without exposure to levonorgestrel.</u></p> <p><b>15. OTHER PRECAUTIONS</b></p> <p><b>15.1 Information Based on Clinical Use</b></p> <p><u>External genital abnormality has been reported in infants born to women who used other progestogen preparations, although not for the purpose of emergency contraception.</u></p>
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(References) Zhang,L.,et al.:Human Reproduction 2009;24(7):1605-1611

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