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Revision of Precautions

Nifedipine

December 5, 2022

Therapeutic category

Vasodilators

Non-proprietary name

Nifedipine

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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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	Revised
Contraindications Pregnant women (less than 20 weeks of pregnancy) or women who may be pregnant	Contraindications (deleted)
Use during Pregnancy, Delivery, or Lactation This drug should not be administered to pregnant women (less than 20 weeks of pregnancy) or women who may be pregnant. [Teratogenicity and foetal toxicity have been reported in animal studies.]	Use during Pregnancy, Delivery, or Lactation (deleted)
This drug should be administered to women after 20 weeks of pregnancy only if the potential therapeutic benefits are considered to outweigh the potential risks. [The safety of this drug administered during pregnancy has not been established.] Prior to administration, the latest relevant guidelines, etc. should be referred to. In order to avoid acute and excessive decrease in blood pressure, basically, long-acting preparations of this drug should be administered with a full understanding of the characteristics of each preparation. In addition, mothers, foetuses, and neonates should be carefully monitored. If any abnormalities such as excessive decrease in blood pressure and decrease in foetal placental circulation are	This drug should be administered to pregnant women or women who may be pregnant only if the potential therapeutic benefits are considered to outweigh the potential risks. [Teratogenicity and foetal toxicity have been reported in animal studies.] Prior to administration, the latest relevant guidelines, etc. should be referred to. In order to avoid acute and excessive decrease in blood pressure, basically, long-acting preparations of this drug should be administered with a full understanding of the characteristics of each preparation. In addition, mothers, foetuses, and neonates should be carefully monitored. If any abnormalities such as excessive decrease in blood pressure and decrease in foetal placental circulation are

observed, appropriate measures should be taken. [In cases of administration to pregnant women, excessive decrease in blood pressure, etc. have been reported.]	observed, appropriate measures should be taken. [In cases of administration to pregnant women, excessive decrease in blood pressure, etc. have been reported.]

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	Revised
2. CONTRAINDICATIONS Pregnant women (less than 20 weeks of pregnancy) or women who may be pregnant	2. CONTRAINDICATIONS (deleted)
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women This drug should not be administered to pregnant women (less than 20 weeks of pregnancy) or women who may be pregnant. Teratogenicity and foetal toxicity have been reported in animal studies. This drug should be administered to women after 20 weeks of pregnancy only if the potential therapeutic benefits are considered to outweigh the potential risks. Prior to administration, the latest relevant guidelines, etc. should be referred to. In order to avoid acute and excessive decrease in blood	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women (deleted) This drug should be administered to pregnant women or women who may be pregnant only if the potential therapeutic benefits are considered to outweigh the potential risks. Teratogenicity and foetal toxicity have been reported in animal studies. Prior to administration, the latest relevant guidelines, etc. should be

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