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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Angiotensin-converting enzyme inhibitors
Preparations containing angiotensin II receptor blocker
Aliskiren fumarate

May 9, 2023

Therapeutic category

Antihypertensives

Vasodilators

Non-proprietary name

Azilsartan

Azilsartan/amlodipine besilate

Alacepril

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Aliskiren fumarate

Imidapril hydrochloride

Irbesartan

Irbesartan/amlodipine besilate

Irbesartan/trichlormethiazide

Enalapril maleate

Olmesartan medoxomil

Olmesartan medoxomil/azelnidipine

Captopril

Candesartan cilexetil

Candesartan cilexetil/amlodipine besilate

Candesartan cilexetil/hydrochlorothiazide

Temocapril hydrochloride

Delapril hydrochloride

Telmisartan

Telmisartan/amlodipine besilate

Telmisartan/amlodipine besilate/hydrochlorothiazide

Telmisartan/hydrochlorothiazide

Trandolapril

Valsartan

Valsartan/amlodipine besilate

Valsartan/cilnidipine

Valsartan/hydrochlorothiazide

Benazepril hydrochloride

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Perindopril erbumine

Lisinopril hydrate

Losartan potassium

Losartan potassium/hydrochlorothiazide

Safety measure

Precautions should be revised.

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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
Use in Pregnant, Parturient and Nursing Women (N/A)	Use in Pregnant, Parturient and Nursing Women Women of child-bearing potential should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential risks. Prior to administration, the necessity of administration of this drug should be carefully considered, taking into account whether alternative drugs are available, etc. If administration is considered necessary, attention should be paid to the following points. (1) Prior to administration of this drug, the absence of pregnancy should be confirmed. Also, during administration of this drug, the absence of pregnancy should be confirmed periodically. When pregnancy is detected, administration of this drug should be discontinued immediately. (2) The following matters should be explained to patients at the start of administration of this drug. In addition, an explanation should be provided during administration when necessary. • This drug can cause foetal and neonatal harm when administered to a pregnant woman. • If pregnancy is detected or suspected, the attending physician should be consulted immediately. • If pregnancy is planned, the attending physician should be

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	consulted. [Cases have been reported in which angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers were used in women without recognizing that they were pregnant, and foetal and neonatal adverse events (renal failure, aplasia of skull, lung, and kidney, death, etc.) were observed.]

[References] Shinya Abe, et al.: Perinatal Medicine. 2017;47:1353-1355.

Daisuke Saito, et al.: Kagoshima Journal of Obstetrics and Gynecology. 2021;29:49-54.

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

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

Revised language is underlined.

Current	Revision
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.4 Patients with Reproductive Potential Women of child-bearing potential Cases have been reported in which angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers were used in women without recognizing that the women were pregnant, and foetal and neonatal adverse events (renal failure, aplasia of skull, lung, and kidney, death, etc.) were observed. Prior to administration, the necessity of administration of this drug

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	should be carefully considered, taking into account whether alternative drugs are available, etc., and this drug should be administered only if the potential therapeutic benefits are considered to outweigh the potential risks. If administration is considered necessary, attention should be paid to the following points. (1) Prior to administration of this drug, the absence of pregnancy should be confirmed. Also, during administration of this drug, the absence of pregnancy should be confirmed periodically. When pregnancy is detected, administration of this drug should be discontinued immediately. (2) The following matters should be explained to patients at the start of administration of this drug. In addition, an explanation should be provided during administration when necessary. • This drug can cause foetal and neonatal harm when used to a pregnant woman. • If pregnancy is detected or suspected, the attending physician should be consulted immediately. • If pregnancy is planned, the attending physician should be consulted.

[References] Shinya Abe, et al.: Perinatal Medicine. 2017;47:1353-1355.
Daisuke Saito, et al.: Kagoshima Journal of Obstetrics and Gynecology. 2021;29:49-54.

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