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Revision of Precautions

Sacubitril valsartan sodium hydrate

May 9, 2023

Therapeutic category

Antihypertensives

Other cardiovascular agents

Non-proprietary name

Sacubitril valsartan sodium hydrate

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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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 9.4 Patients with Reproductive Potential	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.4 Patients with Reproductive Potential Women of childbearing potential 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. Prior to administration, the necessity of administration of this drug 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 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.

Women of childbearing potential should be instructed to use appropriate contraceptive methods for a certain period during and after the administration of this drug.	(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. • Appropriate contraceptive methods should be used for a certain period during and after the administration of this drug. • 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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