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
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
Perindopril erbumine
Lisinopril hydrate
Losartan potassium
Losartan potassium/hydrochlorothiazide

**Safety measure**
Precautions should be revised.
Use in Pregnant, Parturient and Nursing Women
(N/A)

<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
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<tbody>
<tr>
<td>Use in Pregnant, Parturient and Nursing Women</td>
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<tr>
<td>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...</td>
<td></td>
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</table>
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

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.

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<td>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS (N/A)</td>
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<td>9.4 Patients with Reproductive Potential</td>
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<td>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.</td>
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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.

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