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Translated by
Pharmaceuticals and Medical Devices Agency



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

Losartan potassium/hydrochlorothiazide

November 16, 2022

Therapeutic category

Antihypertensives

Non-proprietary name

Losartan potassium/hydrochlorothiazide

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	Revision
<p>Adverse Reactions Clinically Significant Adverse Reactions Interstitial pneumonia, pulmonary oedema</p>	<p>Adverse Reactions Clinically Significant Adverse Reactions Interstitial pneumonia, pulmonary oedema, <u>acute respiratory distress syndrome:</u> <u>Interstitial pneumonia, pulmonary oedema may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken immediately. In addition, it has been reported that acute respiratory distress syndrome developed within minutes to hours after taking hydrochlorothiazide.</u></p>

(References) Rai,A.,et al.:Am.J.Respir.Crit.Care Med. 2016;193:A1890

Jansson,P.S.,et al.:J.Emerg.Med. 2018;55:836-840

Vadas,P.:Am.J.Emerg.Med. 2020;38:1299,e1-2

Kane,S.P.,et al.:Perfusion 2018;33:320-322

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>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions</p>	<p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions</p>

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Interstitial pneumonia, pulmonary oedema	Interstitial pneumonia, pulmonary oedema, <u>acute respiratory distress syndrome</u> <u>Interstitial pneumonia, pulmonary oedema may occur. In addition, it has been reported that acute respiratory distress syndrome developed within minutes to hours after taking hydrochlorothiazide.</u>
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