Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Candesartan cilexetil/hydrochlorothiazide

Valsartan/hydrochlorothiazide

November 16, 2022

Therapeutic category

Antihypertensives

Non-proprietary name

Candesartan cilexetil/hydrochlorothiazide

Valsartan/hydrochlorothiazide

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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
Adverse Reactions Clinically Significant Adverse Reactions Pulmonary oedema: Pulmonary oedema may occur. Patients should be monitored carefully. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken immediately.	Adverse Reactions Clinically Significant Adverse Reactions Pulmonary oedema, acute respiratory distress syndrome: Pulmonary oedema may occur. Patients should be monitored carefully. 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.

(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
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Pulmonary oedema	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Pulmonary oedema, acute respiratory distress syndrome

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

	Pulmonary oedema may occur. In addition, it has been reported that acute respiratory distress syndrome developed within minutes to hours after taking hydrochlorothiazide.

(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

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp