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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

Hydrocortisone

Hydrocortisone sodium succinate

Hydrocortisone sodium phosphate

July 20, 2021

Therapeutic category

Adrenal hormone preparations

Non-proprietary name

Hydrocortisone, hydrocortisone sodium phosphate, hydrocortisone sodium succinate

Pharmaceuticals and Medical Devices Agency

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

Safety measure

Precautions should be revised in the package insert.

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
Pediatric Use (N/A)	Pediatric Use <u>Occurrence of transient hypertrophic cardiomyopathy in neonates and infants has been reported. Neonates and infants should be carefully monitored by cardiac function tests (such as echocardiogram) as necessary prior to and during administration of this drug.</u>

Reference: Vimala,J.,et al.:Int.J.Cardiol. 2011;150(3):e94-95

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

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.7 Pediatric Use</p> <p>(N/A)</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.7 Pediatric Use</p> <p><u>Occurrence of transient hypertrophic cardiomyopathy in neonates and infants has been reported. Neonates and infants should be carefully monitored by cardiac function tests (such as echocardiogram) as necessary prior to and during administration of this drug.</u></p>

Reference: Vimala, J., et al.: Int. J. Cardiol. 2011;150(3):e94-95

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