

Published by
Ministry of Health, Labour and Welfare



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

Adrenaline

(preparations indicated for prolonged action of local anaesthetics and for prevention and treatment of local haemorrhage during surgery)

December 21, 2020

Therapeutic category

Adrenal hormone preparations

Non-proprietary name

Adrenaline

Safety measure

Precautions should be revised in the package insert.

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
<p>Precautions concerning Use</p> <p>Use as an additive to local anaesthetics:</p> <p>As an additive to local anaesthetics, this drug should not be used in ears, digits, or penis.</p>	<p>Precautions concerning Use</p> <p>Use as an additive to local anaesthetics:</p> <p>As an additive to local anaesthetics <u>other than lidocaine injections</u>, this drug should not be used in ears, digits, or penis.</p> <p><u>As an additive to lidocaine injections, caution should be exercised as follows:</u></p> <ul style="list-style-type: none"> · <u>This drug should not be used in penis.</u> · <u>For patients with systemic or peripheral blood flow disorder, patients who are to receive simultaneous injections to multiple digits, and pediatric patients, appropriateness of administration should be considered carefully if anaesthesia is intended for ears or digits. (A necrotic condition may occur.) If administration is decided upon, measures such as reducing the dose of this drug should be taken as appropriate.</u>

Pharmaceuticals and Medical Devices Agency

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