This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Corticorelin (human)

September13, 2016

Non-proprietary name

Corticorelin (human)

Brand name (Marketing authorization holder)

hCRH “TANABE” Injection 100 mg (Mitsubishi Tanabe Pharma Corporation)

Indications

Secretory function test of hypothalamic, pituitary, and adrenocortical hormone

<Judgment criteria>

Secretory function is determined by the blood adrenocorticotropic hormone (ACTH) level and the blood cortisol level.

Because the blood ACTH level varies depending on measurement methods, the time-of-day of testing, and other conditions, normal response criteria should be developed in each institution. When the testing is performed for a healthy individual at around 9:00 a.m., radioimmunoassay measurement normally shows that the blood ACTH level (approximately 15 pg/mL before administration) reaches the maximum level 30 minutes after administration to approximately 3 times the level before administration. However, when the blood ACTH level 30 minutes after administration alone is considered insufficient as the basis to determine the secretory function, it is desirable that the blood ACTH level is chronologically measured after administration to determine the secretory function.

Because the blood cortisol level varies depending on measurement methods, the time-of-day of testing, and other conditions, normal response criteria should be developed in each institution. When the testing is performed for a healthy individual at around 9:00 a.m., radioimmunoassay measurement normally shows that the blood cortisol level

(approximately 10 μg/mL before administration) reaches the maximum level 60 minutes after administration to 2 times the level before administration. However, when the blood cortisol level 60 minutes after administration alone is considered insufficient as the basis to determine the secretory function, it is desirable that the blood cortisol level is chronologically measured after administration to determine the secretory function.

Summary of revision

"Shock and anaphylaxis" should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of shock and anaphylaxis have been reported in patients treated with corticorelin (human) in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 2 cases associated with shock and anaphylaxis has been reported (a causal relationship to the product could not be ruled out for both cases). No fatality has been reported.

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