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Summary of Investigation Results

Aciclovir (oral dosage form and injection)

Valaciclovir hydrochloride

February 10, 2026

Non-proprietary name

- a. Aciclovir (oral dosage form and injection)
- b. Valaciclovir hydrochloride

Brand name (marketing authorization holder)

- a. Zovirax Granules 40%, Zovirax Tablets 200, 400, Zovirax for I.V. infusion 250 (GlaxoSmithKline K.K.), and the others
- b. Valtrex Granules 50%, Valtrex Tablets 500 (GlaxoSmithKline K.K.), and the others

Japanese market launch

- a. Granules 40%: September 1994, Tablets 200: October 1988, Tablets 400: April 1992, I.V. infusion 250: August 1985
- b. Granules 50%: July 2002, Tablets 500: October 2000

Indications

See attachment.

Summary of revisions

“Acute generalised exanthematous pustulosis” should be added to the 11.1 Clinically Significant Adverse Reactions section of 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving acute generalised exanthematous pustulosis were evaluated. Cases in



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which a causal relationship of acute generalised exanthematous pustulosis to aciclovir (oral dosage form and injection) or valaciclovir hydrochloride was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases*¹ and patient mortalities involving acute generalised exanthematous pustulosis reported in Japan*² and overseas*³

a. No cases have been reported in Japan to date.

b. A total of 3 cases have been reported in Japan to date (including 2 cases in which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported in Japan to date.

a. A total of 2 cases have been reported overseas to date. (A causal relationship between the drug and the event was reasonably possible for these cases).

No patient mortalities have been reported overseas to date.

b. One case has been reported overseas to date. (A causal relationship between the drug and the event was reasonably possible for this case.)

No patient mortalities have been reported overseas to date.

*1: Cases retrieved from those collected in the PMDA's safety database for drugs

*2: Cases describing pustule observation were extracted from the cases reported with "PT: Acute generalised exanthematous pustulosis" (MedDRA ver. 28.0.)

*3: Cases describing pustule observation were extracted from the cases reported with "PT: Acute generalised exanthematous pustulosis" (MedDRA ver. 28.0) presented by the marketing authorization holder as the rationale for revision of the CCDS were evaluated.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc.", by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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Attachment

	Nonproprietary name	indications
a.	Aciclovir	<p>Granules 40% [Adult patients]</p> <ul style="list-style-type: none"> • Treatment of herpes simplex • Risk reduction of herpes simplex virus infection at the time of hematopoietic stem cell transplantation • Treatment of herpes zoster <p>[Pediatric patients]</p> <ul style="list-style-type: none"> • Treatment of herpes simplex • Risk reduction of herpes simplex virus infection at the time of hematopoietic stem cell transplantation • Treatment of herpes zoster • Treatment of varicella • Risk reduction of recurrent genital herpes <p>Tablets 200, 400 [Adult patients]</p> <ul style="list-style-type: none"> • Treatment of herpes simplex • Risk reduction of herpes simplex virus infection at the time of hematopoietic stem cell transplantation • Treatment of herpes zoster <p>[Pediatric patients]</p> <ul style="list-style-type: none"> • Treatment of herpes simplex • Risk reduction of herpes simplex virus infection at the time of hematopoietic stem cell transplantation • Treatment of herpes zoster • Risk reduction of recurrent genital herpes <p>I.V. infusion 250</p> <ul style="list-style-type: none"> • Treatment of the following infections caused by the herpes simplex virus or varicella zoster virus Herpes simplex, varicella, herpes zoster in immunocompromised patients (patients with malignant tumour or autoimmune disease for example) Encephalitis, meningitis • Treatment of neonatal herpes simplex virus infection
b.	Valaciclovir hydrochloride	<ul style="list-style-type: none"> • Treatment of herpes simplex • Risk reduction of herpes simplex virus infection at the time of hematopoietic stem cell transplantation • Treatment of herpes zoster • Treatment of varicella • Risk reduction of recurrent genital herpes