

Summary of Investigation Results

Amenamevir

Non-proprietary name	Non-proprietary name	Brand name (marketing authorization holder)
Brand name	Amenamevir	Amenalief Tablets 200 mg (Maruho Co., Ltd.)
Japanese market launch	September 2017	
Indications	○ Herpes zoster ○ Recurrent herpes simplex	
Summary of revisions	"Anaphylaxis" should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving anaphylaxis were evaluated. Cases in which a causal relationship between amenamevir and anaphylaxis was reasonably possible have been reported. For this reason, MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	
Reference: Number of cases* involving anaphylaxis reported in Japan	A total of 12 cases have been reported to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.	

*: Cases collected in PMDA's safety database for drugs.