

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Tirabrutinib hydrochloride

July 17, 2024

Therapeutic category

Other antitumor agents

Non-proprietary name

Tirabrutinib hydrochloride

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revised language is underlined.

Current			Revision		
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION If adverse reactions occur following administration of this drug, this drug should be discontinued temporarily or permanently, or the dose should be reduced by referring to the following criteria. A guide for temporary/permanent drug discontinuation or dose reduction in the event of adverse reactions			7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION If adverse reactions occur following administration of this drug, this drug should be discontinued temporarily or permanently, or the dose should be reduced by referring to the following criteria. A guide for temporary/permanent drug discontinuation or dose reduction in the event of adverse reactions		
Adverse reactions*		Treatment	Adverse reactions*		Treatment
Skin disorders	Grade 2	Antihistamines, corticosteroids, etc. should be administered. If the patient recovers from adverse reactions, administration of this drug should be continued. If the patient does not recover from adverse reactions, administration of this drug should be continued by reducing the dose by one level or administration of this drug should be temporarily discontinued.	Skin disorders	Grade 2	Antihistamines, corticosteroids, etc. should be administered. If the patient recovers from adverse reactions, administration of this drug should be continued. If the patient does not recover from adverse reactions, administration of this drug should be continued by reducing the dose by one level or administration of this drug should be temporarily discontinued.
	Grade 3 or higher	Antihistamines, corticosteroids, etc. should be administered, and administration of this drug should be		Grade 3 or higher	Antihistamines, corticosteroids, etc. should be administered, and administration of this drug should be

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		temporarily discontinued until adverse reactions recover to grade 2 or lower. After the recovery, administration can be resumed by reducing the dose by one level.			temporarily discontinued until adverse reactions recover to grade 2 or lower. After the recovery, administration can be resumed by reducing the dose by one level.
* Grade should be in accordance with NCI-CTCAE v4.0.				<u>Oculomucocutaneous syndrome (Stevens-Johnson syndrome) or toxic epidermal necrolysis (TEN)</u>	<u>Administration should be permanently discontinued.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Severe skin disorders Severe skin disorders such as erythema multiforme or toxic skin eruption may occur.			* Grade should be in accordance with NCI-CTCAE v4.0. 11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Severe skin disorders Severe skin disorders such as <u>toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme,</u> or toxic skin eruption may occur.		

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