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.

<table>
<tr><th>Current</th><th>Revision</th></tr>
<tr><td>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
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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.

* 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 erythema multiforme or toxic skin eruption may occur.

		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.
	Oculomucocutaneous syndrome (Stevens-Johnson syndrome) or toxic epidermal necrolysis (TEN)	Administration should be permanently discontinued.

* 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 toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme, or toxic skin eruption may occur.