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.

IMPORTANT

June, 2021 No.21-01

Dear Healthcare Professionals Letter of Rapid Safety Communication BLUE LETTER

Shock and anaphylaxis by Joyclu 30mg intra-articular injection

Since its marketing approval on March 23, 2021, a total of 10 cases of serious shock and anaphylaxis have been reported in patients treated with this drug as of May 28 (estimated number of patients who have received this drug: approximately 5 500[Note]).
One of the cases was reported to have led to death, although the causal relationship with the drug is unknown. Taking account of these situations, we have decided to newly add a WARNING section and to revise IMPORTANT PRECAUTIONS section in the PRECATIONS of the package insert of the drug to alert concerned parties to this safety concern.

Note) Number of patients who have received this drug from marketing approval to May 28, 2021.

When using this drug, please exercise caution regarding the following:

- Serious shock and anaphylaxis may occur following administration of this drug. Sufficient preparation for emergency responses should be ensured prior to administration.
- Patients should be carefully monitored for at least 30 minutes following administration for their conditions under the supervision of a physician. It should be noted that cases of shock and anaphylaxis following administration of this drug have not been reported with an onset immediately after administration alone. Cases in which shock and anaphylaxis occurred after the patients went back home was reported.
- Patients or their caregivers, etc., should be informed adequately that shock and anaphylaxis may occur, with its signs and symptoms, and that patients should seek medical attention immediately if any abnormalities are observed.

Contact:
Distributor: Ono Pharmaceutical Co., Ltd Medicine Consultation Service
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Revision of Precautions

Revision by the instruction from MHLW　　Revised language is underlined.

Revision	Current
1. WARNINGS Serious shock and anaphylaxis may occur following administration of this drug. Sufficient preparation for emergency responses should be ensured prior to administration. Patients should be carefully monitored after administration of this drug. 8. IMPORTANT PRECAUTIONS Serious shock and anaphylaxis may occur following administration of this drug. Sufficient preparation for emergency responses should be ensured prior to administration. Patients should be carefully monitored during and after administration of this drug. Patients and their caregivers, etc., should be adequately informed that shock and anaphylaxis may occur, with signs and symptoms, and that patients should seek medical attention immediately if any abnormalities are observed.	(N/A) 8. IMPORTANT PRECAUTIONS (N/A)

N/A: Not Applicable, because the section is not included in the current package insert or no corresponding language is included in the section.