



# Summary of investigation results

## Oxytocin

### Non-proprietary name

Oxytocin

### Brand name (Marketing authorization holder)

Atonin-O Injection 1 unit, 5 units (ASKA Pharmaceutical Co., Ltd.), and others

### Indications

Atonin-O Injection is used for the induction and enhancement of uterine contractions and the treatment of uterine bleeding in the following cases:

Induction of labor, uterine inertia, atonic bleeding, before and after placental delivery, uterine subinvolution, Caesarean section (after delivery of the fetus), abortion, artificial abortion

### Summary of revision

“Anaphylaxis” should be newly added to the “Shock” subsection in the Clinically significant adverse reaction section.

### Background of the revision and investigation results

Cases of anaphylaxis have been reported in patients treated with oxytocin in Japan.

Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

### The number of reported adverse reactions and fatal cases in the last three fiscal years in Japan

A total of 5 cases associated with anaphylaxis have been reported (including 3 cases for which a causal relationship to the product could not be ruled out; however, 1 case was for a condition which was contraindicated in the package insert\*). No fatality has been reported.



**Pharmaceuticals and Medical Devices Agency**

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*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.*

**NOTE:**

\* Patient with previously demonstrated hypersensitivity to this product

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