

# Medical Safety Information

Pharmaceuticals and Medical Devices Agency

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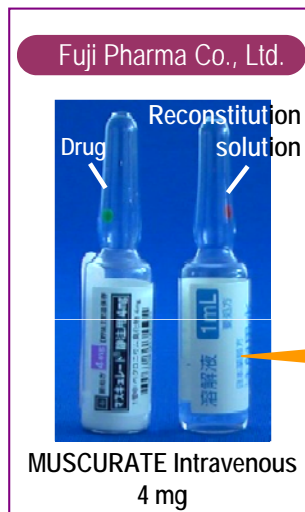
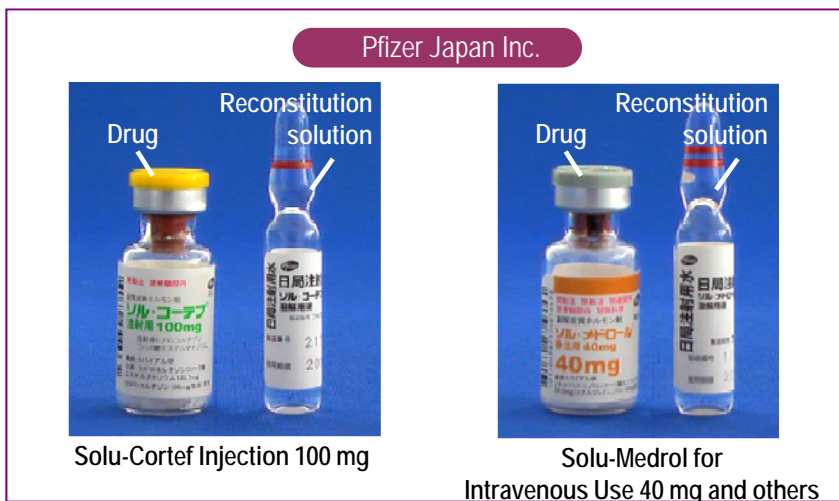
## Precautions in Handling of Drug Products Attached with Reconstitution Solution

### POINT Key points for safe use

**(Case 1)** A resident was instructed to administer an intravenous steroid injection to a patient. However, the resident administered only the reconstitution solution to the patient for consecutive days.

#### 1 Handling precautions (part 1)

- Before injection, be aware that some injection drugs come with reconstitution solutions to be mixed. Make sure to check the label.



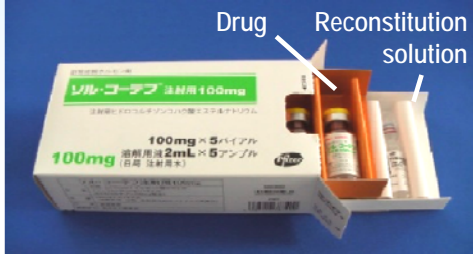
**Cases of administering the reconstitution solution alone** have been reported in these products. Many other injection drugs come with reconstitution solution. **The drug formulary should be checked** to take preventive actions against dosing errors.

\* Reconstitution solution

Note) Photos showing Japanese products.

### Cause of dosing errors: package types

#### Two-tiered package



#### Alternating package



The drug vials and reconstitution solution vials are packed alternately in the same box.

#### Separate packages



The drug vials and reconstitution solution vials are packed in separate boxes.



There are a variety of types of product packages. Be careful not to take out only the reconstitution solution from the box!

In some cases, **only the reconstitution solution was taken out** of the emergency cart by mistake and administered.

**Storing the drug and the reconstitution solution together** as shown in the right could be helpful to avoid dosing errors!

#### Example 1



Keep the vials together with a rubber band.

#### Example 2



Circle individual pairs with a marker pen.

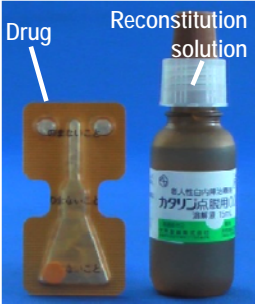





**(Case 2)** A pharmacist dispensed to the ward only the reconstitution solution, which should be mixed with BESTRON FOR OPHTHALMIC. A ward nurse administered only the reconstitution solution to the patient for consecutive days without being aware of it.



**2 Handling precautions (part 2)**

- Before use, be aware that some topical drugs come with reconstitution solutions to be mixed. Make sure to check the label.



**Senju Pharmaceutical Co., Ltd.**

 <p>Drug Reconstitution solution</p> <p><b>CATALIN FOR OPHTHALMIC 0.005%</b></p>	 <p>Drug Reconstitution solution</p> <p><b>CATALIN-K FOR OPHTHALMIC 0.005%</b></p>	 <p>Drug Reconstitution solution</p> <p><b>BESTRON FOR OPHTHALMIC 0.5%</b></p>	 <p>Drug Reconstitution solution</p> <p><b>BESTRON FOR EAR AND NOSE 1%</b></p>
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**Santen Pharmaceutical Co., Ltd.**

 <p>Drug Reconstitution solution</p> <p><b>Ecolicin ophthalmic solution</b></p>	 <p>Drug Reconstitution solution</p> <p><b>Pivalephrine ophthalmic solution 0.1% and others</b></p>
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**Nitto Medic Co., Ltd.**

 <p>Drug Reconstitution solution</p> <p><b>Pirenoxine for Ophthalmic 0.005% "NITTO"</b></p>	 <p>Drug Reconstitution solution</p> <p><b>Erycoli for Ophthalmic Solution T</b></p>
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**Astellas Pharma Inc.**




Drug Reconstitution solution

**\*Tathion 2% for Ophthalmic**

**The following ways could be helpful to indicate whether or not the drug has been dissolved in the solution!**

**Example 1**


\* The data of dissolution



Write the date of dissolution.

**Example 2**

\* Reconstitution solution



Put a sticker on the cap after dissolving the drug.

Put a sticker on the container to indicate the drug has been dissolved in the solution.

\*Astellas Pharma Inc. transferred Tathion 2% for Ophthalmic to Choseido Pharmaceutical Co., Ltd.





(Case 3) The medical staff administered only the reconstitution solution to a patient. The staff was unaware that the vial of Enbrel for S.C. injection was stored in the refrigerator.

### 3 Handling precautions (part 3)

- When the drug and the reconstitution solution are stored separately due to different storage temperatures, caution should be exercised to avoid using only the reconstitution solution.

#### Enbrel for S.C. injection

##### Drug vials



To be stored in a cool place

##### Subcutaneous injection set

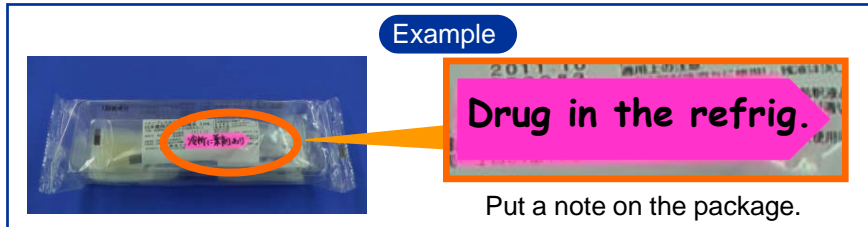


To be stored at room temperature

Note) Photos showing Japanese products.

Putting a note on the package of reconstitution solution could be helpful to indicate that the drug is stored in a different place (e.g., in the refrigerator).

#### Example



Put a note on the package.



#### About this information

- \* PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Affairs Law.
- \* We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.
- \* This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.