

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 19 September, 2010

Administration error of concentrated potassium (K) solutions for injection

POINT Key points for safe use

(Case 1) When a dipotassium phosphate corrective solution (20 mL) was to be administered by mixing with total parenteral nutrition, it was confused with a drug solvent (5% glucose, 20 mL) for another treatment and intravenously administered by single shot injection via Y-site injection port.

1 Precautions when handling concentrated potassium solutions

- Always reconfirm the drug's **label and administration method** before use.

Potassium solution

Single shot intravenous injection is contraindicated.

For drip infusion only (dilution required)

Be careful of misreading!

Undiluted potassium solution being intravenously administered by single shot injection could cause **arrhythmia and cardiac arrest**, which is very dangerous.

Possible causes of mix-ups

Mix-up due to container shape



Drugs stored together could cause misidentification. Make sure to store/manage concentrated potassium solutions separately from other drugs.



Mix-up due to solution color, etc.



KCL Corrective Injection 1 mEq/mL
(Otsuka Pharmaceutical Factory, Inc.)



OTSUKA GLUCOSE INJECTION 5%
(Otsuka Pharmaceutical Factory, Inc.)



Dipotassium Phosphate
Corrective Injection 1 mEq/mL
(Otsuka Pharmaceutical Factory, Inc.)

Do not imagine all concentrated potassium solutions are yellow!



Cases where mix-up was caused by wrong assumptions about container shape and solution color has been reported. You must **confirm the label carefully** and **have more than one person do the checking!**

(Case 2) For potassium replacement, the order was to mix 2 ampoules of concentrated potassium solutions with total parenteral nutrition before administration. However, by mistake, it was intravenously administered by single shot via Y-site injection port in the patient route.

Concentrated potassium solution products that require precautions during handling

Potassium chloride solution products



For drip infusion only; administer diluted

K.C.L. DRIP INJECTION 15%
 (Maruishi Pharmaceutical Co., Ltd.)



For drip infusion only (dilution required)

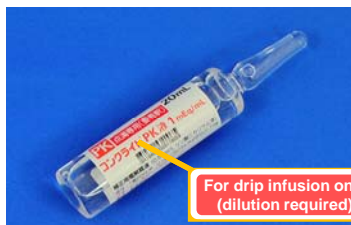
Conclyte Solution-K 1 mEq/mL
 (Nipro Pharma Corporation)



For drip infusion only (dilution required)

KCL Corrective Injection 1 mEq/mL
 (Otsuka Pharmaceutical Factory, Inc.)

Dipotassium phosphate solution products



For drip infusion only (dilution required)

Conclyte PK Solution 1 mEq/mL
 (Nipro Pharma Corporation)



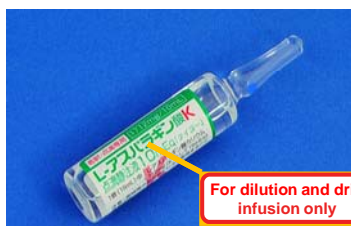
For drip infusion only (dilution required)

Dipotassium Phosphate Corrective Injection 1 mEq/mL
 (Otsuka Pharmaceutical Factory, Inc.)

When these products are drawn into a syringe and put on a tray, there is a risk of improper administration method.



Potassium aspartate solution products



For dilution and drip infusion only

L-ASPARTATE K
 (Taiyo Yakuhin Co., Ltd.)



Dilution required!

ASPARA Potassium Injection 10mEq
 (Mitsubishi Tanabe Pharma Corporation)



Dilution required

ASPARA Injection
 (Mitsubishi Tanabe Pharma Corporation)



Dilution required

ISEPARA-K Injection 17.12%
 (ISEI Co., Inc.)



Dilution; drip infusion

Armokarin Inj. 10mEq
 (Nissin Pharmaceutical Co., Ltd.)



Dilution required

ELSPRI INJECTION 10mEq
 (Towa Pharmaceutical Co., Ltd.)

* The following organizations also release safety information concerning precautions in handling concentrated potassium solutions.

- Japanese Nursing Association <http://www.nurse.or.jp/nursing/practice/anzen/pdf/20060718.pdf>
- The Japanese Board of Cardiovascular Surgery <http://cvs.umin.jp/topic/040602.html>

2 Products with safeguards to prevent single shot intravenous injection



KCL Injection 10mEq Kit "Terumo"
(Terumo Corporation)



Potassium L-Aspartate Injection 10mEq Kit "Terumo"
(Terumo Corporation)



KCL Injection 20mEq Kit "Terumo"
(Terumo Corporation)

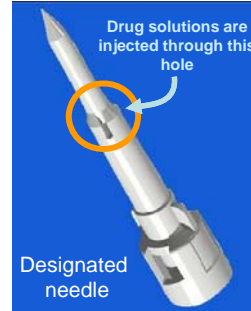


Dibasic Potassium Phosphate Injection
20mEq Kit "Terumo" (Terumo Corporation)



The tip having an external screw, **only designated needles can be connected**. Therefore, medical standard three-way stopcocks and injection needles cannot be connected to it, as they have external screws.

(Figure: Supplied by Terumo Corporation)



(Figure: Supplied by Terumo Corporation)

Drug solutions are not injected through the needle tip. Therefore, even if devices other than infusion bags are connected, drug solutions cannot be injected.

To prevent accidents, pharmaceutical safety management supervisors as well as risk managers are **encouraged to consider switching to products with safeguards to prevent inadvertent administration** such as described above.



The Ministry of Health, Labour and Welfare (MHLW) has issued safety information that are related to the issues in this PMDA Medical Safety Information No. 19.

- June 2004 Pharmaceuticals and Medical Devices Safety Information No. 202
"Safety measures relating to pharmaceuticals with high risks resulting from mix-ups"

Information on this notification is available at the website of Pharmaceuticals and Medical Devices Safety Information (issued by MHLW):

http://www.pmda.go.jp/english/service/precautions_2004.html

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.