ตารางเปรียบเทียบฉลากถุงของ CAPD/DPCA3

No	ฉลากที่ได้รับอนุมัติ	ฉลากที่ขอแก้ไข
1	HONG KONG, BANGLADESH, PAKISTAN CAPD/DPCA 3 Solution for peritoneal dialysis	HONG KONG, PAKISTAN CAPD/DPCA 3 Solution for peritoneal dialysis
	I liter contains: Calcium chloride dihydrate Sodium chloride Sodium (S)-lactate solution Sodium (S)-lactate Magnesium chloride hexahydrate	1 liter contains: Calcium chloride dihydrate Sodium chloride Sodium (S)-lactate solution Sodium (S)-lactate Magnesium chloride hexahydrate
	Glucose monohydrate anhydrous glucose Water for injections, hydrochloric acid, sodium hydroxide.	Glucose monohydrate anhydrous glucose Water for injections, hydrochloric acid, sodium hydroxide. Sterile and free from bacterial endotoxins. Do not use unless solution is clear and container undamaged. For single use. Any unused portion of the solution should be discarded. For intraperitoneal use only. Solution is not to be used for intravenous infusion. Keep out of the reach and sight of children. Read the package leaflet before use. To be used only as directed by a medical practitioner. Do not store above 25°C. Do not refrigerate or freeze. 請遵照醫 生指示使用,請勿將產品貯存於攝 氏25度以上。請勿將產品冷藏或冷 凍。 Prescription Drug 處方藥物 HK-36486
	Sterile and free from bacterial endotoxins. Do not use unless solution is clear and container undamaged. For single use. Any unused portion of the solution should be discarded. For intraperitoneal use only. Solution is not to be used for intravenous infusion. Keep out of the reach and sight of children. Read the package leaflet before use. To be used only as directed by a medical	
	practitioner. Do not store above 25°C. Do not refrigerate or freeze. 請遵照醫生指示使用,請勿將產品貯存於攝氏25度以上。請勿將產品冷藏或冷凍。	
	HK-36486	Fresenius Medical Care Pakistan Pvt. Ltd., TAMC, First Floor 27-C III, M.M. Alam Road, Gulberg III, Lahore 54660, Pakistan) Registration Number 039886 MRP: PKR 400/ 2000 ml bag)

<u>เดิม</u> มีการระบุประเทศ Bangladesh และไม่มีการแสดงข้อมูล Imported and Marketed ของประเทศ Pakistan <u>แก้ไขเป็น</u> ยกเลิกการระบุประเทศ Bangladesh และแสดงข้อมูลของประเทศ Pakistan

แก้ไข ข้อมูลรายละเอียดผู้นำสั่งประเทศ India และ Philippines

3





แก้ไข โลโก้บริษัท

ตารางเปรียบเทียบฉลากกล่องของ CAPD/DPCA3

No.	ฉลากที่ได้รับอนุมัติ	ฉลากที่ขอแก้ไข
1	HONG KONG / BANGLADESH / PAKISTAN CAPD/DPCA 3 Solution for peritoneal dialysis	HONG KONG / PAKISTAN CAPD/DPCA 3 Solution for peritoneal dialysis
	Sodium chloride Sodium (S)-lactate solution Sodium (S)-lactate solution Sodium (S)-lactate Magnesium chloride hexahydrate Glucose monohydrate sarhydrous glucose Water for injections, hydrochloric soid, sodium hydroxide. Sterile and free from bacterial endotoxins. Do not use unless solution is clear and container undamaged. For single use. Any unused portion of the solution should be discarded. For intrasperitoreal use ently. Solution is not to be used for intravenous infusion. Keep out of the reach and sight of children. Read the package leaflet before use. To be used only as directed by a medical practitioner. Do not store above 25°C. Do not refrigerate or freeze. 講演照歷生指示使用,請勿將產品貯存於攝氏25度以上。請勿將產品冷藏或冷凍。 HK-36486	1 liter contains: Calcium chloride dihydrate
		Sodium chloride Sodium (S)-lactate solution Sodium (S)-lactate Magnesium chloride hexahydrate Glucose monohydrate anhydrous glucose Water for injections, hydrochloric acid, sodium hydroxide. Sterile and free from bacterial endotoxins. Do not use unless solution is clear and container undamaged. For single use. Any unused portion of the solution should be discarded. For intraperitoneal use only. Solution is not to be used for intravenous infusion. Keep out of the reach and sight of children. Read the package leaflet before use. To be used only as directed by a medical practitioner. Do not store above 25°C. Do not refrigerate or freeze. 請遵照醫生指示使用,請勿將產品貯存於攝氏25度以上。請勿將產品冷藏或冷凍。 Prescription Drug 處方藥物 HK-36486
		Imported and Marketed by: Fresenius Medical Care Pakistan Pvt. Ltd.) TAMC, First Floor 27-C III, M.M. Alam Road, Gulberg III, Lahore 54660, Pakistan Registration Number 039886 MRP: PKR 400/ 2000 ml bag

เดิม มีการระบุประเทศ Bangladesh และไม่มีการแสดงข้อมูล Imported and Marketed ของประเทศ Pakistan

<u>แก้ไขเป็น</u> ยกเลิกการระบุประเทศ Bangladesh และแสดงข้อมูลของประเทศ Pakistan

No.

ฉลากที่ได้รับอนุมัติ

ฉลากที่ขอแก้ไข

2

INDIA

CAPD/DPCA 3 I.P.

Solution for Peritoneal Dialysis

1 liter contains:

Calcium chloride dihydrate

Sodium chloride

Sodium (S)-lactate solution

Sodium (S)-lactate

Magnesium chloride hexahydrate

Glucose monohydrate

anhydrous glucase Water for injections, hydrochloric acid, sodium hydroxide.

Sterile and free from bacterial endobins. Do not use unless solution is clear and container undamaged. For single use. Any unused portion of the solution is to be discarded. For intraperitoneal use only. Solution is not to be used for intravenous infusion. Keep out of reach and sight of children. Read the package insert before use. To be used only as directed by a medical practitioner. Do not store above 25°C. Do not refrigerate or freeze.

Imported by: Gautem Healthcare.

230 Anarkali Complex, Jhandewalan Extension,

New Dehi 110055, India, Import License no.: FF-552-18264

Marketed By-Fresenius Medical Care India Pvt. Ltd.,

11 th Floor, Front wing, Dr. Gopal Dass Bhawan, 28-Barakhamba Road,

New Dehi - 110001, India, Import License no. FF-552-17460 MRP(Inclusive of Taxes) : Re 3507- Multi-lingual, multi-country label

PHILIPPINES

Peritoneal Dialysis Solution with Dextrose 4.25%

Peritoneal Dialysis Solution

1 liter contains:

Calcium chloride dihydrate

Sodium chloride

Sodium (S)-lactate solution

Sodium (S)-lactate

Magnesium chloride hexahydrate

Dextrose

Water for injections, hydrochloric acid, sodium hydroxide.

Sterile and free from bacterial endotoxins (non-pyrogenic). Do not use unless solution is clear and container undamaged. For single use. Any unused portion of the solution is to be discarded! For intraperitoneal use only. Solution is not to be used for intravenous infusion. Do not store above 25°C. Do not refrigerate or freeze. Keep out of the reach and sight of children! Read the package insert before use.

Imported /Distributed by: Fresenius Medical Care Philippines, Inc. 18/F, Aeon Center, Corner Alabang-Zapote Road and North Bridgeway, Filinvest. Corporate City, Alabang Muntinlupa City 1781, Philippines Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

DR-XY39968

INDIA

CAPD/DPCA 3

Solution for Peritoneal Dialysis I.P

1 liter contains:

Calcium chloride dihydrate

Sodium chloride

Sodium (S)-lactate solution

Sodium (S)-lactate

Magnesium chloride hexahydrate

Glucose monohydrate

anhydrous glucose

Water for injections, hydrochloric acid, sodium hydroxide.

Sterile and free from bacterial endotoxins. Do not use unless solution is clear and container undamaged. For single use. Any unused portion of the solution is to be discarded. For intraperitoneal use only. Solution is not to be used for intravenous infusion. **Keep out of reach and sight of children.** Read the package insert before use. To be used only as directed by a medical practitioner. Do not store above 25°C. Do not refrigerate or freeze.

Imported and Marketed By:

Fresenius Medical Care India Pvt. Ltd.,

B7 & B8, Middle Portion, SIPCOT Industrial Park, Irungattukottai,

Sriperumbudur, Chennai, 602105, India

Import License No.: FF-552-24961

MRP: Rs 350 (Inclusive of all taxes) per Bag Multi-lingual, multi-country label

PHILIPPINES

Peritoneal Dialysis Solution with Dextrose 4.25%

Peritoneal Dialysis Solution

1 liter contains:

Calcium chloride dihydrate

Sodium chloride

Sodium (S)-lactate solution

Sodium (S)-lactate

Magnesium chloride hexahydrate

Dextrose

Water for injections, hydrochloric acid, sodium hydroxide.

Sterile and free from bacterial endotoxins (non-pyrogenic). Do not use unless solution is clear and container undamaged. For single use. Any unused portion of the solution is to be discarded! For intraperitoneal use only. Solution is not to be used for intravenous infusion. Do not store above

25°C. Do not refrigerate or freeze. Keep out of the reach and sight of children! Read the package insert before use.

Imported / Distributed by: Fresenius Medical Care Philippines, Inc. 18/F, Aeon Center, Corner Alabang-Zapote Road and North Bridgeway, Filinvest Corporate City, Alabang Muntinlupa City 1781, Philippines Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription. For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph)

DR-XY39968

<u>แก้ไข</u> ข้อมูลรายละเอียดผู้นำสั่งประเทศ India และ Philippines

No.	ฉลากที่ได้รับอนุมัติ	ฉลากที่ขอแก้ไข
3	Fresenius Medical Care	FRESENIUS MEDICAL CARE
แก้ไข	โลโก้บริษัท	