

05 July 2024

Dear Patient,

### Alternate Supply Arrangement for Extraneal AHB5546R

This letter is to advise of an alternate supply arrangement for the Australian registered medicine, Extraneal 7.5% w/v Icodextrin Peritoneal Dialysis Solution - AHB5546R (AUST R91344).

For a temporary period, you will be supplied with Extraneal FNB4974SG. This is the same Extraneal constitute that you are currently using, and is sourced from Baxter's Singapore manufacturing facility. We expect supply of FNB4974SG to continue through to June 2025.

There are some minor differences in the way FNB4974SG is packaged as described below. All other elements are the same.

### PRODUCT ORDER CODE

The product code of your existing Extraneal supply is AHB5546R.

The product code of the new Extraneal to be supplied is FNB4974SG.

This code will be automatically updated on your order form.

### BAG VOLUME AND PACK FACTOR

FNB4974SG is a 2,000mL bag of Extraneal and is delivered in a carton containing six bags (versus five bags of 2,500mL Extraneal AHB5546R).

If you have an Extraneal Last Fill volume of greater than 2,000mL, please contact your dialysis unit to discuss possible changes to your prescription.

### CARTON

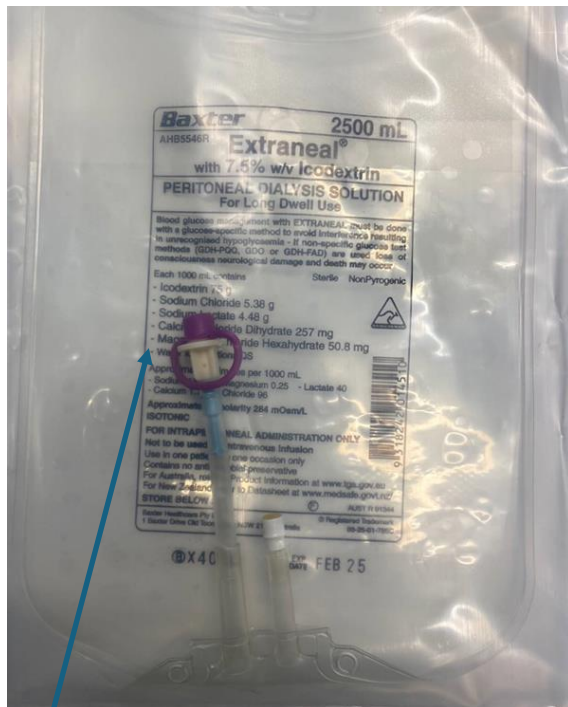


The outer carton of FNB4974SG contains an orange sticker with product details (including lot number and expiry date) as opposed to these details being printed directly onto the carton in the case of AHB5546R.

Similarly, the tape used to secure the carton of FNB4974SG is clear with a green tab for ease of opening, as opposed to the white tape with purple text on AHB5546R.

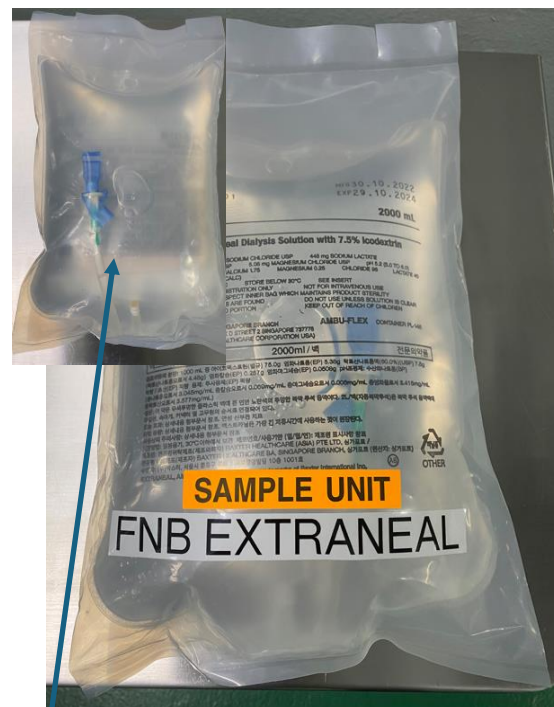
## SOLUTION BAG

AHB5546R



Purple ring pull with blue frangible Luer positioned on printed side of bag

FNB4974SG



Blue ring pull with green frangible Luer positioned on non-printed side of bag



The design of the blue ring pull on the FNB4974SG is slightly different. However, the operation is very similar and demonstrated in this image.

Similarly, there are some differences on the solution bag label.

**Baxter**
**2500 mL**

AHB5546R

**Extraneal®**  
 with 7.5% w/v Icodextrin

**PERITONEAL DIALYSIS SOLUTION**  
 For Long Dwell Use

Blood glucose management with EXTRANEAL must be done with a glucose-specific method to avoid interference resulting in unrecognised hypoglycaemia. If non-specific glucose test methods (GDH-PQQ, GDO or GDH-FAD) are used loss of consciousness neurological damage and death may occur

Each 1000 mL contains                      Sterile    NonPyrogenic

- Icodextrin 75 g
- Sodium Chloride 5.38 g
- Sodium Lactate 4.48 g
- Calcium Chloride Dihydrate 257 mg
- Magnesium Chloride Hexahydrate 50.8 mg
- Water for Injections QS

Approximate millimoles per 1000 mL

- Sodium 132      - Magnesium 0.25      - Lactate 40
- Calcium 1.75      - Chloride 96

Approximate Osmolality 284 mOsm/L

**ISOTONIC**

**FOR INTRAPERITONEAL ADMINISTRATION ONLY**

**Not to be used for intravenous infusion**

Use in one patient on one occasion only

Contains no antimicrobial preservative

For Australia, refer to Product Information at [www.tga.gov.au](http://www.tga.gov.au)

For New Zealand, refer to Datasheet at [www.medsafe.govt.nz/](http://www.medsafe.govt.nz/)

**STORE BELOW 30°C**                                           AUST R 91344

Baxter Healthcare Pty Ltd                      © Registered Trademark  
 1 Baxter Drive Old Toongabbie NSW 2146 Australia                      88-25-01-785C

## FNB4974

ยาเส้นอายุ  
**2000 mL**  
 (APPROX 80 mL EXCESS)

### Baxter

#### EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin

**EACH 100 mL CONTAINS**

7.5 g ICODEXTRIN	538 mg SODIUM CHLORIDE USP	448 mg SODIUM LACTATE
25.7 mg CALCIUM CHLORIDE USP	5.08 mg MAGNESIUM CHLORIDE USP	pH 5.2 (5.0 TO 6.0)
mmol/L SODIUM 132	CALCIUM 1.75	MAGNESIUM 0.25
		CHLORIDE 96
		LACTATE 40

**OSMOLARITY** 284 mOsm/L (CALC)

**STERILE**    NONPYROGENIC    STORE BELOW 30°C    SEE INSERT

**FOR INTRAPERITONEAL ADMINISTRATION ONLY**    NOT FOR INTRAVENOUS USE

**CAUTIONS**    SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY

DISCARD IF LEAKS ARE FOUND    DO NOT USE UNLESS SOLUTION IS CLEAR

DISCARD UNUSED PORTION    KEEP OUT OF REACH OF CHILDREN

MANUFACTURED BY

**BAXTER HEALTHCARE SA, SINGAPORE BRANCH**

2 WOODLANDS INDUSTRIAL PARK D STREET 2 SINGAPORE 737778

(AN AFFILIATE OF BAXTER HEALTHCARE CORPORATION USA)

**DIRECTION**    TO BE USED AS DIRECTED BY PHYSICIAN

FOR HONG KONG ONLY: PRESCRIPTION DRUG    處方藥物

IMPORTED BY **BAXTER HEALTHCARE (THAILAND) CO., LTD., BANGKOK**

FOR MALAYSIA ONLY: CONTROLLED MEDICINE. JAUHI DARIPADA KANAK-KANAK

**PRODUCT REGISTRATION HOLDER:**

**BAXTER HEALTHCARE (MALAYSIA) SDN. BHD.,**

B-21-3A, THE ASCENT, PARADIGM, 1, JLN SS7/26A, 47301 PJ SELANGOR, MALAYSIA

#### "百特" 愛多尼爾腹膜透析液

衛署藥輸字第 023687 號                      本藥限由醫師使用                      批號及保存期限詳如包裝所示

請詳閱說明書                      百特醫療產品股份有限公司                      台北市敦化南路2段95號28樓

**EXTRANEAL, AMBU-FLEX and PL-146** are trademarks of Baxter International Inc.

**REMINDER** - blood glucose management with Extraneal should be done with a glucose-specific method to avoid interference resulting in unrecognised hypoglycaemia. If non-specific glucose test methods or test strips are used loss of consciousness, neurological damage and death may occur. Further details can be found in your Extraneal Patient Kit or at [www.glucouyoursesafety.com](http://www.glucouyoursesafety.com).

#### TIMING OF ALTERNATE SUPPLY

You will start to see Extraneal FNB4974SG in your deliveries in the coming weeks.

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with Extraneal FNB4974SG should be reported by healthcare professionals and patients to Baxter Healthcare on 1800 920 133 or [ANZ.MedicalInformation@vantive.com](mailto:ANZ.MedicalInformation@vantive.com). Alternatively, this information can be reported to the TGA.

We have contacted your healthcare team to advise them of this temporary change and appreciate this change may cause some inconvenience. We are focused on securing the ongoing supply of Extraneal and appreciate your patience as we transition to this alternative supply.

For further information, please contact your dialysis unit or Baxter Healthcare on 1800 920 133.

Yours faithfully,

Matthew Bain  
 General Manager – Renal Care  
 Baxter Healthcare Australia

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