EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin
License No. 023687

Prescription drug only
For intraperitoneal administration only

Product name
EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin

Composition
EXTRANEAL is a sterile solution for intraperitoneal administration.
Each 100 mL of EXTRANEAL contains:
- Icodextrin 7.5 g
- Sodium Chloride 538 mg
- Sodium Lactate 448 mg
- Calcium Chloride 25.7 mg
- Magnesium Chloride 5.08 mg
- Electrolyte solution content per 1000 mL:
  - Sodium 132 mmol
  - Calcium 1.75 mmol
  - Magnesium 0.25 mmol
  - Chloride 96 mmol

Theoretical osmolality 284 (milliosmole per liter).

Excipient
EXTRANEAL also contains: Water for injections.

Pharmaceutical form and Pharmaceutical Properties
EXTRANEAL is a sterile peritoneal dialysis fluid containing icodextrin as the active ingredient at a concentration of 7.5%, in an electrolyte solution. It should not be used for intravenous administration.

EXTRANEAL is presented in flexible PVC containers and is available in the following bag sizes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Fill Volume (mL)</th>
<th>Container Size (mL)</th>
<th>Product Configuration</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>FNB4974</td>
<td>2000</td>
<td>2000</td>
<td>AMBU-FLEX</td>
<td>6</td>
</tr>
<tr>
<td>FNB4982</td>
<td>1500</td>
<td>2000</td>
<td>LLLTRABAG</td>
<td>8</td>
</tr>
<tr>
<td>FNB4984</td>
<td>2000</td>
<td>2000</td>
<td>LLLTRABAG</td>
<td>6</td>
</tr>
</tbody>
</table>

Properties
Icodextrin is a starch-derived glucose polymer which acts as an osmotic agent when administered intraperitoneally for continuous ambulatory peritoneal dialysis (CAPD). EXTRANEAL produces sustained ultrafiltration over a period up to 12 hours in CAPD, with a reduction in caloric load compared to 4.25% Dextrose solutions, but with similar volume of ultrafiltrate.

Therapeutic Indications
EXTRANEAL is recommended for the treatment of chronic renal failure.

Contraindications
EXTRANEAL is contraindicated in patients with:
- a known allergy to starch-based polymers (e.g. corn starch) and/or icodextrin
- malabsorption or isomaltase intolerance
- glycosgen storage disease
- pre-existing severe lactic acidosis
- uncorrectable mechanical defects that prevent effective PD or increase the risk of infection
- documented loss of peritoneal function or extensive adhesions that compromise peritoneal function

Precautions for Use
- EXTRANEAL is intended for intraperitoneal administration only. Not for intravenous administration.
- To change the dialysis bag, it is of vital importance that all the steps shown during training are carefully followed and to ensure that all the connecting parts remain completely clean to reduce the possibility of infection.
- Do not administer if the solution is discolored, cloudy, contains particulate matter or shows evidence of leakage or if seals are not intact.
- The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.
- Safety and effectiveness in pediatric patients have not been established.
- Proteins, amino acids, water-soluble vitamins, and other medicines may be lost during peritoneal dialysis and may require replacement.

- Peritoneal dialysis should be done with caution in patients with:
  1) abdominal conditions, including disruption of the peritoneal membrane and diaphragm by surgery, from congenital anomalies or trauma until healing is complete, abdominal tumors, abdominal wall infection, hernias, fecal fistula, colostomy, or ileostomy, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polyptic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity; and
  2) other conditions including anorectal graft placement and severe pulmonary disease.
- An accurate fluid balance record should be kept and the patient's body weight monitored. Patients should be carefully monitored to avoid over- and underhydration.
- Overfiltration of an EXTRANEAL volume into the peritoneal cavity may be characterized by abdominal distension, feeling of fullness and/or shortness of breath.
- Treatment of EXTRANEAL overfiltration is to drain the EXTRANEAL from the peritoneal cavity.
- Potassium is omitted from EXTRANEAL solutions due to the risk of hyperkalemia.
- In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia and should be made after careful evaluation of serum and total body potassium, only under the direction of a physician.
- Fluid, electrolyte, blood chemistry, and electrolyte concentrations should be monitored periodically, including: magnesium and bicarbonate. If serum magnesium levels are low, oral magnesium supplements or peritoneal dialysis solutions containing higher magnesium concentrations may be used.
- In diabetic patients, blood glucose levels should be regularly monitored, and the dosage of insulin or other treatment for hyperglycemia should be adjusted following initiation of treatment with EXTRANEAL.
- Decreases in serum sodium and chloride have been observed in patients using EXTRANEAL.

Special Warnings
Blood glucose measurement must be done with a glucose-specific method to prevent maltose interference.

Glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GOD) – based methods must not be used.

Also, the use of some glucose monitors and test strips using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) methodology has resulted in falsely elevated glucose readings due to the presence of maltose. The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose results.

If GDH-PQQ, GOD, or GOD-FAD-based methods are used, using EXTRANEAL may cause a falsely high glucose reading, which could result in the administration of more insulin than needed. Administration of more insulin than needed has caused hypoglycemia, which has resulted in loss of consciousness, coma, neurological damage, and death.

Additionally, falsely elevated blood glucose measurements due to maltose interference may mask true hypoglycemia and allow it to go untreated with similar consequences.

Falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GOD, or GDH-FAD-based blood glucose monitors and test strips are used.

Because GDH-PQQ, GOD, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of all peritoneal dialysis patients using EXTRANEAL (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with EXTRANEAL (icodextrin).

To avoid improper insulin administration, educate all patients on EXTRANEAL therapy to alert health care providers of this interaction whenever they are admitted to the hospital.

Encapsulating peritoneal sclerosis (EPS) is considered to be a known, raw complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including EXTRANEAL. Infrequently, fatal outcomes of EPS have been reported with EXTRANEAL.

If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be indicated.

Rarely, serious hypersensitivity reactions to EXTRANEAL have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactoid/anaphylactic reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected
Dosage and Method of Administration

Dosage

The volume to be instilled should be given over a period of approximately 10 to 20 minutes at a rate which patients find comfortable. For adult patients of normal body size the instilled volume should not exceed 2.0 litres. If this causes abdominal tension a 1.5 litre volume should be used. The recommended dwell time is between 6 and 12 hours in CAPD and 14-16 hours in AFD.

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**Hypersensitivity Reaction**

A variety of therapeutic countermeasures must be instituted as clinically indicated.

- Patients with severe lactic acidosis should not be treated with lactate-based peritoneal dialysis solutions. (See Contraindications) It is recommended that patients with conditions known to increase the risk of lactic acidosis [e.g., severe hypothermia or sepsis that can be associated with acute renal failure; blood volume loss due to metabolic waste; treatment with drugs such as metformin and nucleotide/nucleotide reverse transcriptase inhibitors (NRTIs)] must be monitored for occurrence of lactic acidosis before the start of treatment and during treatment with lactate-based peritoneal dialysis solutions.

- When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. Serum potassium levels should be monitored carefully in patients treated with cardiac glycosides.

**Pregnancy and Lactation**

There are no adequate data from the use of EXTRANEAL in pregnant or lactating women. EXTRANEAL is not recommended during pregnancy or while breast feeding. Women of childbearing potential should be treated with EXTRANEAL only when adequate contraceptive precautions have been taken. Potential effects on male and female fertility are unknown.

**Interactions with other Medicaments and other Forms of Interaction**

No interaction studies have been conducted with EXTRANEAL. The blood concentration of dialyzable drugs may be reduced by peritoneal dialysis.

**Drug-Laboratory Test Interferences**

- Blood glucose measurement must be done with a glucose-specific method to prevent malsee interference. Glucose dehydrogenase pyrrolquinoline quinine (GDP-PQQ), glucose-dye-oxidoreductase (GDO)-based methods must not be used. Also, the use of some glucose monitors and test strips using glucose dehydrogenase flavin adenine dinucleotide (GDP-FAD) methodology has resulted in falsely elevated glucose readings due to the presence of malose. See Special Warnings and Precautions for use.

- An apparent decrease in serum amylase activity has been observed in patients administered EXTRANEAL.

Patients using cardiac glycosides should carefully monitor blood electrolyte levels, such as calcium, potassium, magnesium.

**Effects on Ability to Drive and Use Machines**

End stage renal disease (ESRD) patients undergoing peritoneal dialysis may experience undesirable effects, which could affect the ability to drive or use machines.

**Incompatibilities**

- Consult with pharmacist familiar with peritoneal dialysis, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aspecific technique.

- Refer to directions for use accompanying drugs to obtain full information on additives.

- Some drug additives may be incompatible with EXTRANEAL.

  > Addition of Potassium

  - Potassium is omitted from EXTRANEAL solutions because dialysis may be performed to correct hyperkalemia. In situations where there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. The decision to add potassium chloride should be made by the physician after careful evaluation of serum potassium.

  > Addition of Insulin

  - Addition of insulin to EXTRANEAL was evaluated in 6 insulin-dependent diabetic patients undergoing CAPD for end stage renal disease. No interference of EXTRANEAL with insulin absorption from the peritoneal cavity or with insulin's ability to control blood glucose was observed. (See Interactions With Other Medications Products and Other Forms of Interaction). Appropriate monitoring of blood glucose should be performed when initiating EXTRANEAL in diabetic patients and insulin dosage adjusted if needed. (See Special Warnings and Precautions for Use).

  > Addition of Heparin

  - No human drug interaction studies with heparin were conducted. In vitro studies demonstrated no evidence of incompatibility of heparin with EXTRANEAL.

  > Addition of Antibiotics

  - No formal clinical drug interaction studies have been performed. In vitro compatibility studies with EXTRANEAL and the following antibiotics have demonstrated no effect with regard to minimum inhibitory concentration (MIC): vancomycin, cephalaxin, ampicillin/sulbactam, cefazidime, gentamicin, and amphotericin. However, aminoglycosides should not be mixed with penicillins due to chemical incompatibility.

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**Adverse Reactions**

The adverse reactions within this section represent those that are thought to have an association with use of EXTRANEAL or in conjunction with performing the peritoneal dialysis procedure.

**Adverse Reactions from Clinical Trials**

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**Clinical Trial Adverse Reactions**

**System Organ Class (SOC)**

<table>
<thead>
<tr>
<th>Preferred MedDRA Term</th>
<th>Frequency*</th>
<th>Frequency Percentage or Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFECTIONS AND INFESTATIONS</td>
<td>Influenza</td>
<td>Uncommon</td>
</tr>
<tr>
<td></td>
<td>Furuncle</td>
<td>Uncommon</td>
</tr>
<tr>
<td></td>
<td>Infection</td>
<td>Uncommon</td>
</tr>
<tr>
<td>BLOOD AND LYMPHATIC SYSTEM DISORDERS</td>
<td>Anemia</td>
<td>Uncommon</td>
</tr>
<tr>
<td></td>
<td>Leukocytosis</td>
<td>Uncommon</td>
</tr>
<tr>
<td></td>
<td>Eosinophilia</td>
<td>Uncommon</td>
</tr>
</tbody>
</table>

**ENDOCRINE DISORDERS**

Parathyroid disorder

**METABOLISM AND NUTRITION DISORDERS**

- Dehydration
- Hypovolemia
- Hypoglycemia
- Hypernatremia
- Hyperkalemia
- Hypercalcemia
- Anorexia
- Hypophosphatemia
- Hypomagnesemia
- Hypoproline

**PSYCHIATRIC DISORDERS**

- Thinking abnormal
- Anxiety
- Nervousness

**NERVOUS SYSTEM DISORDERS**

- Dizziness
- Headache
- Hypertension
- Dizziness
- Anxiety
- Nervousness

**EACH AND LARYNEX DISORDERS**

- Tinnitus

**CARDIAC DISORDERS**

- Cardiovascular disorder
- Tachycardia

**VASCULAR DISORDERS**

- Hypertension
- Hypotension
- Orthostatic hypotension

**RESPIRATORY, THORACIC AND MEDIAL DISORDERS**

- Pulmonary edema
- Dyspnea
- Cough
- Hiccups
- Lung disorder

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Administration:

- EXTRANEAL is intended for intraperitoneal administration only. Not for intravenous administration.

- EXTRANEAL should be administered at a rate that is comfortable for the patient. The volume administered is determined by the prescribing physician.

- The mode of therapy, frequency of treatment, exchange volume, duration of dwell and length of dialysis should be initiated and supervised by the physician.

- Peritoneal dialysis solutions may be warmed in the overip to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad, warming plate) should be used. Solutions should not be heated in water or in a microwave oven due to the potential for patient injury or discomfort.

- Aseptic technique should be employed throughout the peritoneal dialysis procedure.

- Do not administer if the solution is discolored, cloudy, contains particulate matter or shows evidence of leakage, or if seals are not intact.

- The drained fluid should be inspected for the presence of fibrin or clotted blood, which may indicate the presence of peritonitis.

- Discard any unused remaining solution.

- For single use only.

Special Populations:

- Adults:
- Use is limited to a single daily exchange for the long dwell, as part of a peritoneal dialysis regimen.

- Elderly:
- As for adults.

- Pediatrics:
- EXTRANEAL is not recommended in children.

Safety and effectiveness in pediatric patients have not been established.
### Clinical Trial Adverse Reactions ¹

<table>
<thead>
<tr>
<th>System Organ Class (SOC)</th>
<th>Preferred MedDRA Term</th>
<th>Frequency</th>
<th>Frequency Percentage or Ratio N=493</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GASTROINTESTINAL DISORDERS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>Common</td>
<td>1.6</td>
<td></td>
</tr>
<tr>
<td>Abdominal distension</td>
<td>****</td>
<td>¹</td>
<td></td>
</tr>
<tr>
<td>Intestinal obstruction</td>
<td>Uncommon</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Peritonitis</td>
<td>Uncommon</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Bloody peritoneal effluent</td>
<td>Uncommon</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>Uncommon</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Gastric ulcer</td>
<td>Uncommon</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Gastritis</td>
<td>Uncommon</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Gastrintestinal disorder</td>
<td>Uncommon</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>Uncommon</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>Uncommon</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>Uncommon</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>Uncommon</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Dry Mouth</td>
<td>Uncommon</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Flatulence</td>
<td>Uncommon</td>
<td>0.2</td>
<td></td>
</tr>
</tbody>
</table>

| **SKIN AND SUBCUTANEOUS DISORDERS** | | | |
| Dermatitis exfoliative | Common | 1.6 |
| Rash | Common | 5.5 |
| Pruritus | Common | 1.4 |
| Urticaria | Uncommon | 0.2 |
| Dermatitis bullous | Uncommon | 0.2 |
| Psoriasis | Uncommon | 0.4 |
| Rash/macule-papular | Uncommon | 0.2 |
| Skin ulcer | Uncommon | 0.2 |
| Eczema | Uncommon | 0.2 |
| Nail disorder | Uncommon | 0.6 |
| Skin disorder | Uncommon | 0.2 |
| Dry skin | Uncommon | 0.2 |
| Skin discoloration | Uncommon | 0.2 |

| **MUSCULOSKELETAL, CONNECTIVE TISSUE DISORDERS** | | | |
| Bone pain | Uncommon | 0.1 |
| Muscle spasms | Uncommon | 0.4 |
| Myalgia | Uncommon | 0.4 |
| Neck pain | Uncommon | 0.6 |

| **RENAL AND URINARY DISORDERS** | | | |
| Renal pain | Uncommon | 0.2 |

| **GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS** | | | |
| Edema peripheral | Common | 1.4 |
| Asthenia | Common | 1.2 |
| Chest pain | Uncommon | 0.4 |
| Catheter-related complication | Uncommon | 0.2 |
| Face edema | Uncommon | 0.2 |
| Edema | Uncommon | 0.6 |
| Pain | Uncommon | 0.2 |

| **INVESTIGATIONS** | | | |
| Urine output decreased | | **** |
| Laboratory test abnormal | | **** |
| Alanine aminotransferase increased | Common | 2.6 |
| Aspartate aminotransferase increased | Uncommon | 0.4 |
| Blood alkaline phosphatase increased | Uncommon | 0.4 |
| Liver function test abnormal | Uncommon | 0.6 |
| Weight decreased | Uncommon | 0.2 |
| Weight increased | Uncommon | 0.6 |

| **INJURY, POISONING, AND PROCEDURAL COMPLICATIONS** | | | |
| Injury | Uncommon | 0.2 |

¹ Lower level term

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### EYE DISORDERS: Vision blurred

**RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS**: Bronchospasm, Stridor

**GASTROINTESTINAL DISORDERS**: Serosing encapsulating peritonitis, Aspergillus peritonitis*, Peritoneal cloudy effluent, Ileus, Acute, Inguinal hernia, Abdominal discomfort

**SKIN AND SUBCUTANEOUS DISORDERS**: Toxie epidermal necrolysis, Erythema multiforme, Angioedema, Urticaria generalized, Toxie skin eruption, Swelling face, Periorbital edema, Exfoliative rash, Skin exfoliation, Prurige, Rash (including muscular, papular, erythematous), Dermatitis (including allergic and contact), Drug eruption, Erythema, Onychomadesis, Skin chapped, Blisters

**MUSCULOSKELETAL, CONNECTIVE TISSUE DISORDERS**: Arthralgia, Back pain, Musculoskeletal pain

**REPRODUCTIVE SYSTEM AND BREAST DISORDERS**: Penile edema, Scrotal edema

**GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS**: Discomfort, Pyrexia, Chills, Malaise, Drug effect decreased, Drug ineffective, Catheter site erythema, Catheter site inflammation, Infusion related reaction (including Infusion site pain, Instillation site pain)

**INJURY, POISONING AND PROCEDURAL COMPLICATIONS**: Device interaction

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### Overdose

Continuous administration of more than one bag of EXTRANEAL in 24 hours would increase plasma levels of carbohydrate metabolites and malaise. The effects of such an increase are unknown, but an increase in plasma osmolality may occur. In the event of overdosage with EXTRANEAL continued peritoneal dialysis with glucose-based solutions should be provided.

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### Preclinical Safety Data

Carcinogenesis, Mutagenesis, Impairment of Fertility

Icodextrin did not demonstrate evidence of genotoxicity potential in in vitro bacterial cell reverse mutation assay (Ames test); in vitro mammalian cell chromosomal aberration assay (CHO cell assay); and in the in vivo micronucleus assay in mice. Long-term animal studies to evaluate the carcinogenic potential of EXTRANEAL or icodextrin have not been conducted. Icodextrin is derived from maltodextrin, a common food ingredient.

A fertility study in rats where males and females were treated for four and two weeks, respectively, prior to mating and until day 17 of gestation at up to 1.5 g/kg/day (1/3 the human exposure on a mg/m² basis) revealed slightly low epidymal weights in parental males in the high dose group as compared to Control. Toxicological significance of this finding was not evident as no other reproductive organs were affected and all males were of proven fertility. The study demonstrated no effects of treatment with icodextrin on mating performance, fertility, litter response, embryo-fetal survival, or fetal growth and development.

### Special Precautions for Storage

EXTRANEAL has a shelf life of 2 years. Do not use the product after expiry date shown on the carton and product label. Store at temperature below 30°C. Do not use unless the solution is clear and the container undamaged.

Keep out of reach of children. Any unused portion of dialysis solution in a bag should be discarded.

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### Name and address of manufacturer

Baxter Healthcare SA, Singapore Branch
2 Woodlands Industrial Park D Street 2, Singapore 737778

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### Date of revision

PDG 25-254 Feb 2015

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僅供腹膜透析

產品名稱
EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin

成份
每 100ml EXTRANEAL 含：
Icodextrin（碳水化合物鍵） 7.5 g
Sodium Chloride（氯化鈉） 538 mg
Sodium Lactate（乳酸） 448 mg
Calcium Chloride（氯化鈣） 25.7 mg
Magnesium Chloride（氯化鎂） 5.08 mg

每 1000 ml 電解質溶液含：
Sodium（鈉） 132 mmol
Calcium（鈣） 1.75 mmol
Magnesium（鎂） 0.25 mmol
Lactate（乳酸） 90 mmol

理論滿容量為 284（millimoles/l/公斤）

說明
EXTRANEAL 亦含有：注射用水。

調製及使用
EXTRANEAL 僅使用於透析專用 PVC 材質中，有下列三種容量裝置：

產品名稱 預混溶液 預混容量 透析儀
FNB4974 2000 ml 2000 ml AMBU-FLX 6
FNB4982 1500 ml 2000 ml 混透 8
FNB4984 1500 ml 2000 ml 混透 8

特性
Icodextrin 為類葡萄糖多聚糖聚合物，主要作用是在透析時可透析透析液（CAPD），並且不產生透壓。EXTRANEAL 在長達 12 小時的透析活動（透析過濾法）中，可有效減少透析液容量，相對於相當於透析液之 42% 類葡萄糖多聚糖透析液，EXTRANAL 可顯著減少透析液透析所需吸熱量之負擔。見血過敏

使用

使用前應該確認透析液的正確性，包括下列方面：

- 調製透析液時，應確保所有透析液容器內應是清潔的。
- 檢查透析液是否與預混溶液相符，以避免使用錯誤的透析液。

注意事項
EXTRANAL 使用前須配備，不可直接注射。

- 更換透析袋，於調製後的各階段都必須使用無菌的手套，以保持無菌狀態。
- 確認透析液的正確性，包括其濃度、成分及有效期。
- 檢查透析液是否混有異物或變質現象。

- 有關透析袋的使用安全及有效性的考量。

- 務必在使用前保持透析液的溫度，以免影響其效果。

- 透析過程中可能會放入有機酸、氨基酸、體內毒素、其他藥物及尿素的溶解。

- 透析過程中應避免使用含類固醇的藥物，如皮質類固醇。

- 透析過程中應避免使用含類固醇的藥物，如皮質類固醇。

- 透析過程中應避免使用含類固醇的藥物，如皮質類固醇。

- 透析後應避免使用含類固醇的藥物，如皮質類固醇。

- 透析後應避免使用含類固醇的藥物，如皮質類固醇。

- 透析後應避免使用含類固醇的藥物，如皮質類固醇。

- 透析後應避免使用含類固醇的藥物，如皮質類固醇。

- 透析後應避免使用含類固醇的藥物，如皮質類固醇。
不相容性

- 在使用前，請詳細閱讀產品的使用說明書，並在使用前詳閱產品標示之使用説明。
- 使用電子診斷儀時，應採用適當的電解液。
- 使用電子診斷儀時，應採用適當的電解液。
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進行

iScendexin在體細胞腫瘤模型的靜脈注射，包括黑色素細胞、大腸癌細胞和巨噬細胞的體細胞腫瘤模型。研究顯示，iScendexin在體細胞腫瘤模型中的治療效果優於安慰劑，因iScendexin的治療效果優於安慰劑的效果。研究證明iScendexin治療的長期效果無異，對治療各型腫瘤無影響。