**BAXTER**

**EXTRANEAL Peritoneal Dialysis Solution**
**with 7.5% Icodextrin**
**For intraperitoneal administration only**

**PATIENT LEAFLET**

**Product name**
**EXTRANEAL (Icodextrin 7.5%)**

**Composition**
EXTRANEAL is a sterile solution for intraperitoneal administration.

| Each 100 ml of EXTRANEAL contains: | | Electrolyte solution content per 1000 ml: | |
|---|---|---|---|
| Icodextrin | 7.5 g | Sodium | 132 mmol |
| Sodium Chloride | 538 mg | Calcium | 1.75 mmol |
| Sodium Lactate | 448 mg | Magnesium | 0.25 mmol |
| Calcium Chloride | 25.7 mg | Chloride | 96 mmol |
| Magnesium Chloride | 5.08mg | Lactate | 40 mmol |

Theoretical osmolarity 284 (milliosmoles per litre).

**Composition in Full**
EXTRANEAL also contains:
Water for injections.

**Pharmaceutical form and Pharmacological 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:

| Code | Fill Volume (mL) | Container Size (mL) | Product Configuration | Pack Size |
|---|---|---|---|---|
| FNB4974 | 2000 | 2000 | AMBU-FLEX | 6 |
| FNB4982 | 1500 | 2000 | ULTRABAG | 8 |
| FNB4984 | 2000 | 2000 | ULTRABAG | 6 |

**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/m$^2$ basis) revealed slightly low epididymal 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.

**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 ultra filtrate.

**Therapeutic Indications**
EXTRANEAL is recommended as a once daily replacement for a single Dextrose exchange as part of a CAPD or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for some categories of patients who have lost ultrafiltration on Dextrose solutions, because it can extend time on CAPD therapy in such patients.

**Contraindications**
EXTRANEAL is contraindicated in patients with
- a known allergy to starch-based polymers (e.g. corn starch) and/or icodextrin
- maltose or isomaltose intolerance
- glycogen 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.
- Protein, 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 polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity; and
  2) other conditions including aortic graft placement and severe pulmonary disease.
- Patients should be carefully monitored to avoid over- and underhydration, which may have severe consequences including congestive heart failure, volume depletion and shock. An accurate fluid balance record should be kept and the patient's body weight monitored.
- Overinfusion 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 overinfusion 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, hematology, 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 (GDO) – 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, GDO, or GDH-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, GDO, or GDH-FAD-based blood glucose monitors and test strips are used.
  Because GDH-PQQ, GDO, 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, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including EXTRANEAL. 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. Anaphylactic/anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate 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 hypotension or sepsis that can be associated with acute renal failure; inborn errors of metabolism; treatment with drugs such as metformin and nucleoside/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 maltose interference. Glucose dehydrogenase pyrroloquinolinequinone(GDH-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 (GDH -FAD) methodology has resulted in falsely elevated glucose readings due to the presence of maltose. See Special Warnings and Precautions for use.
- An apparent decrease in serum amylase activity has been observed in patients administered EXTRANEAL.

**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 aseptic 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 Medicinal 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
    Compatibility has been demonstrated with vancomycin, cefazolin, ceftazidime, gentamicin, and netilmicin. However, aminoglycosides should not be mixed with penicillins due to chemical incompatibility.

    Minimum Inhibitory Concentration (MIC)
    No formal clinical drug interaction studies have been performed. *In vitro* studies with EXTRANEAL and the following antibiotics have demonstrated no effects with regard to minimum inhibitory concentration (MIC): vancomycin, cephazolin, ampicillin/flucoxacillin, ceftazidime, gentamicin, and amphotericin.

**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 APD.

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 overpouch 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. In case of damage, the container should be discarded.
- The drained fluid should be inspected for the presence of fibrin or cloudiness, 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.

**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**

| Clinical Trial Adverse Reactions† | | | |
|---|---|---|---|
| **System Organ Class (SOC)** | **Preferred MedDRA Term** | **Frequency*** | **Frequency Percentage or Ratio N=493** |
| **INFECTIONS AND INFESTATIONS** | **Influenza** | Uncommon | 0.6 |
| | **Furuncle** | Uncommon | 0.2 |
| | **Infection** | Uncommon | 0.2 |
| **BLOOD AND LYMPHATIC SYSTEM DISORDERS** | **Anemia** | Uncommon | 0.4 |
| | **Leukocytosis** | Uncommon | 0.6 |
| | **Eosinophilia** | Uncommon | 0.2 |
| **ENDOCRINE DISORDERS** | **Parathyroid disorder** | -** | -** |
| **METABOLISM AND NUTRITION DISORDERS** | **Dehydration** | Common | 2.0 |
| | **Hypovolemia** | Common | 1.0 |
| | **Hypoglycemia** | Uncommon | 0.4 |
| | **Hyponatremia** | Uncommon | 0.4 |
| | **Hyperglycemia** | Uncommon | 0.2 |
| | **Hypervolemia** | Uncommon | 0.8 |
| | **Anorexia** | Uncommon | 0.8 |
| | **Hypochloremia** | Uncommon | 0.8 |
| | **Hypomagnesemia** | Uncommon | 0.4 |
| | **Hypoproteinemia** | Uncommon | 0.4 |
| **PSYCHIATRIC DISORDERS** | **Thinking abnormal** | Uncommon | 0.2 |
| | | Uncommon | 0.2 |
| | **Anxiety** | Uncommon | 0.2 |
| | **Nervousness** | | |
| **NERVOUS SYSTEM DISORDERS** | **Dizziness** | Common | 1.8 |
| | **Headache** | Common | 1.4 |
| | **Hyperkinesia** | Uncommon | 0.2 |
| | **Paraesthesia** | Uncommon | 0.6 |
| | **Ageusia** | Uncommon | 0.2 |
| **EAR AND LABYRINTH DISORDERS** | **Tinnitus** | Common | 3.6 |
| **CARDIAC DISORDERS** | **Cardiovascular disorder** | Uncommon | 0.2 |
| | **Tachycardia** | Uncommon | 0.2 |
| **VASCULAR DISORDERS** | **Hypotension** | Common | 3.2 |
| | **Hypertension** | Common | 2.6 |
| | **Orthostatic hypotension** | Uncommon | 0.2 |
| **RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS** | **Pulmonary edema** | Uncommon | 0.2 |
| | **Dyspnea** | Uncommon | 0.4 |
| | **Cough** | Uncommon | 0.2 |
| | **Hiccups** | Uncommon | 0.2 |
| | **Lung disorder** | Uncommon | 0.4 |

| Clinical Trial Adverse Reactions† | | | |
|---|---|---|---|
| **System Organ Class (SOC)** | **Preferred MedDRA Term** | **Frequency*** | **Frequency Percentage or Ratio N=493** |
| **GASTROINTES-TINAL DISORDERS** | **Abdominal pain** | Common | 1.6 |
| | **Abdominal distension** | -** | -** |
| | **Intestinal obstruction** | Uncommon | 0.2 |
| | **Peritonitis** | Uncommon | 0.6 |
| | **Bloody peritoneal effluent** | Uncommon | 0.2 |
| | **Diarrhea** | Uncommon | 0.6 |
| | **Gastric ulcer** | Uncommon | 0.2 |
| | **Gastritis** | Uncommon | 0.2 |
| | **Gastrointestinal disorder** | Uncommon | 0.4 |
| | **Vomiting** | Uncommon | 0.2 |
| | **Constipation** | Uncommon | 0.4 |
| | **Dyspepsia** | Uncommon | 0.6 |
| | **Nausea** | Uncommon | 0.2 |
| | **Dry Mouth** | Uncommon | 0.4 |
| | **Flatulence** | Uncommon | 0.2 |
| **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,macula-papular** | Uncommon | 0.2 |
| | **Skin ulcer** | Uncommon | 0.2 |
| | **Eczema** | Uncommon | 0.6 |
| | **Nail disorder** | Uncommon | 0.2 |
| | **Skin disorder** | Uncommon | 0.2 |
| | **Dry skin** | Uncommon | 0.2 |
| | **Skin discolouration** | | |
| **MUSCULO-SKELETAL CONNECTIVE TISSUE DISORDERS** | **Bone pain** | Uncommon | 0.1 |
| | **Muscle spasms** | Uncommon | 0.4 |
| | **Myalgia** | Uncommon | 0.4 |
| | **Neck pain** | Uncommon | 0.4 |
| **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** | Common | 2.6 |
| | **Alanine aminotransferase increased** | Uncommon | 0.4 |
| | **Aspartate aminotransferase increased** | Uncommon | 0.4 |
| | **Blood alkaline phosphatase increased** | Uncommon | 0.6 |
| | **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 |

*Frequency has been evaluated using the following criteria: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

†This table represents an integration of safety data from the following clinical trials of 493 patients: RD-97-CA-130, RD-97-CA-131, ML/IB/001, PRO-Renal-Reg-035, ML/IB/020 (DELIA), ML/IB/011 (DIANA), ML/IB/004 (Midas-2), RD-99-CA-060, and ML/IB/014. The table also includes adverse events from clinical study BLR-PG21. Additionally, safety data from studies BLR-PG22, RD-00-CA-050 and RD-00-CA-022 were reviewed and did not require additions to the clinical trial data presented.

**Reported in 1 of 18 patients who were exposed to EXTRANEAL in clinical trial BLR-PG21. Therefore, estimation of frequency not presented due to limited patient population in clinical trial BLR-PG21.

**Post-Marketing Adverse Reactions**

In addition to the adverse reactions noted in clinical trials, the following adverse reactions have been reported in the post-marketing experience. These reactions are listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity.

INFECTIONS AND INFESTATIONS: Fungal peritonitis, Peritonitis bacterial, Catheter site infection, Catheter related infection

BLOOD AND LYMPHATIC SYSTEM DISORDERS: Thrombocytopenia, Leukopenia

IMMUNE SYSTEM DISORDERS: Vasculitis, Serum sickness, Hypersensitivity

METABOLISM AND NUTRITION DISORDERS: Shock hypoglycemia, Fluid overload, Fluid imbalance

NERVOUS SYSTEM DISORDERS: Hypoglycemic coma, Burning sensation

EYE DISORDERS: Vision blurred

RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS: Bronchospasm, Stridor

GASTROINTESTINAL DISORDERS: Encapsulating peritoneal sclerosis, Aseptic peritonitis*, Peritoneal cloudy effluent, Ileus, Ascites, Inguinal hernia, Abdominal discomfort

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

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

*Lower level term

**Overdose**

Continuous administration of more than one bag of EXTRANEAL in 24 hours would increase plasma levels of carbohydrate metabolites and maltose. 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.

**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.

**MARKETING AUTHORISATION HOLDER**

**Baxter Healthcare (Thailand) Co. Ltd**
Bangkok, Thailand

**Imported and marketed by:**
PT Kalbe Farma Tbk
Bekasi - Indonesia

**Name and address of manufacturer**

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**Date of revision**

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