

EXTRANEAL

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using EXTRANEAL?

EXTRANEAL contains the active ingredients icodextrin, sodium chloride, sodium lactate, calcium chloride dihydrate and magnesium chloride hexahydrate. EXTRANEAL Peritoneal dialysis solution is an alternative fluid to be used in chronic kidney failure patients being treated on peritoneal dialysis. For more information, see Section [1. Why am I using EXTRANEAL?](#) in the full CMI.

2. What should I know before I use EXTRANEAL?

Do not use EXTRANEAL if you have ever had an allergic reaction to EXTRANEAL or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use EXTRANEAL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EXTRANEAL and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use EXTRANEAL?

- Follow all directions given to you by your doctor or nurse or pharmacist carefully.
- EXTRANEAL solutions are intended for use via PD catheter only. Aseptic techniques must be maintained during the bag connection in order to reduce the risk of infection.
- Do not use EXTRANEAL if the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage or if seals are not intact.
- EXTRANEAL bags should be used only once and any unused solution remaining must be discarded.

More instructions can be found in Section [4. How do I use EXTRANEAL?](#) in the full CMI.

5. What should I know while using EXTRANEAL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, surgeon, anaesthetist, dentist, pharmacist or nurse you visit that you are using EXTRANEAL• Follow the instructions from your doctor or nurse on how to carry out peritoneal dialysis.
Things you should not do	<ul style="list-style-type: none">• Do not use EXTRANEAL for intravenous administration.• Do not heat EXTRANEAL in water or in a microwave.• Do not stop using EXTRANEAL without letting your doctor know.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery as EXTRANEAL may cause undesirable effects.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30^o C.• Do not use after the expiry date on the bag.

For more information, see Section [5. What should I know while using EXTRANEAL?](#) in the full CMI.

6. Are there any side effects?

You may experience side effects such as hernia, abdominal pain, bleeding, peritonitis, infection around the catheter and catheter blockage and electrolyte imbalances as part of peritoneal dialysis treatment.

For more information, including full list of possible side effects and what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

EXTRANEAL

Active ingredient(s): *Icodextrin, sodium chloride, sodium lactate, calcium chloride dihydrate and magnesium chloride hexahydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EXTRANEAL. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EXTRANEAL.

Where to find information in this leaflet:

- [1. Why am I using EXTRANEAL?](#)
- [2. What should I know before I use EXTRANEAL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EXTRANEAL?](#)
- [5. What should I know while using EXTRANEAL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using EXTRANEAL?

EXTRANEAL contains the active ingredients icodextrin, sodium chloride, sodium lactate, calcium chloride dihydrate and magnesium chloride hexahydrate. EXTRANEAL is a solution for peritoneal dialysis.

EXTRANEAL Peritoneal dialysis solution is an alternative fluid to be used in chronic kidney failure patients being treated on peritoneal dialysis.

2. What should I know before I use EXTRANEAL?

Warnings

Do not use EXTRANEAL if:

- the expiry date on the pack has passed.
- the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage, or if seals are not intact.
- you are allergic to icodextrin, sodium chloride, sodium lactate, calcium chloride dihydrate and magnesium chloride hexahydrate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have a known allergy to starch based polymers (e.g., corn starch) and/or Icodextrin.
- you have known maltose or isomaltose intolerance or patients with glycogen storage disease.
- you have a disorder of metabolism known as lactic acidosis.
- you have any issues that prevents effective dialysis or increase the likelihood of the infection.
- you have any changes in peritoneal function.

Warning for incorrect blood glucose level:

The active ingredient in EXTRANEAL can interfere with the way you measure your blood glucose. This may result in higher than true blood glucose levels being reported by your monitor. Check with your blood glucose device/monitor manufacturer to see if it is safe to be used when you are on EXTRANEAL.

EXTRANEAL PD solution is not recommended in children.

Check with your doctor if you:

- have injury or surgery or congenital anomalies (birth defects) related to abdominal wall or cavity
- a history of abdominal operations with fibrous adhesions (scar tissue)
- faecal fistula (a passageway from your stomach or bowel to the skin)
- intra-abdominal tumours
- open wounds
- hernia
- Peritonitis
- abdominal wall infection
- have severe abdominal pain, abdominal distension, or vomiting. This can be a sign of encapsulating peritoneal sclerosis, a complication of the peritoneal dialysis therapy that can be fatal
- inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis)
- large polycystic kidneys
- colostomy or ileostomy
- frequent episodes of diverticulitis
- you have a lung disease (especially pneumonia)
- aortic graft replacement
- take any medicines for any other condition

On rare occasions, some people may have severe reactions to EXTRANEAL PD solution. This appears as a severe skin reaction with blistering and peeling of the skin. It can also appear as a swelling of the skin and redness. Occasionally there is also swelling of the blood vessels. **If any of these symptoms appear contact your doctor immediately.**

It is important to keep a record of your fluid levels to avoid overhydration or underhydration. Your doctor will monitor your weight to ensure that you are using the right fluid volumes.

Your doctor will monitor your electrolytes levels (particularly bicarbonate, potassium, magnesium, and calcium) and blood profile, as well as other indicators of your health to ensure they are in safe ranges. It is important to carefully monitor the levels of potassium in

your blood if you are being treated with heart medications called cardiac glycosides.

EXTRANEAL PD solution does not contain potassium. In patients with normal or low potassium levels, your doctor may consider adding potassium to the dialysis solution to prevent the occurrence of very low potassium levels.

You may also need to take a magnesium supplement to keep your magnesium level in the safe range.

Peritoneal dialysis can lead to a **loss of proteins, amino acids, water-soluble vitamins** and **other medicines**. An adequate diet or nutritional supplements may be recommended in order to avoid deficiency states. Some changes in your medicine may be needed.

If you have diabetes requiring insulin, carefully monitor your insulin requirements during and following dialysis with glucose-containing solutions.

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

Aseptic techniques must be maintained during the bag connection in order to reduce the risk of infection. Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis. If you experience peritonitis, your doctor may prescribe antibiotics.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Because peritoneal dialysis may influence the effects of medicines, your doctor may need to change their dosages, especially those:

- for heart failure, such as digoxin. Your doctor will check the level of potassium, calcium, and magnesium in your blood and, if necessary, will take appropriate measures.

Peritoneal dialysis can lead to a **loss of proteins, amino acids, water-soluble vitamins** and **other medicines**. An adequate diet or nutritional supplements may be

recommended in order to avoid deficiency states. Some changes in your medicine may be needed.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EXTRANEAL.

4. How do I use EXTRANEAL?

How much to use

Your doctor will determine the method, duration and frequency of use and the required volume of solution and time in the peritoneal cavity (dwell time).

You must follow the procedures and instructions given by your doctor or nurse every time you do peritoneal dialysis. Contact your doctor if you are having problems or are unsure about any of the techniques.

Adults: Single exchange in each 24 hour-period, as part of a Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) regimen.

Elderly: As for adults.

Children: Not recommended for use in children (less than 18 years).

EXTRANEAL PD solution is recommended for use during the longest dwell period; that is in CAPD usually overnight and in APD for the long daytime dwell.

When to use EXTRANEAL

EXTRANEAL should be used, as prescribed by your doctor.

You must follow the procedures and instructions given by your doctor or nurse every time you do peritoneal dialysis. Contact your doctor if you are having problems or are unsure about any of the techniques or your prescription.

How to use EXTRANEAL for PD

EXTRANEAL PD solution is intended for intraperitoneal administration only. Not for intravenous administration.

Aseptic technique should be observed throughout the procedure.

To reduce discomfort on administration, the solution may be warmed to a temperature of 37°C prior to use. This should be done using dry heat ideally with a warming cabinet. Do not heat EXTRANEAL in water or in a microwave. Do not use EXTRANEAL if the solution is discoloured, 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.

EXTRANEAL bags should be used once, and any unused portion of the solution must be discarded.

If you forget to use EXTRANEAL

EXTRANEAL should be used, as prescribed by your doctor.

If you forget to do an exchange or have used too little solution, contact your doctor for guidance.

If you use too much EXTRANEAL

Overdose by over infusion of a EXTRANEAL Solutions into the peritoneal cavity is characterised by abdominal pain and abdominal stretching and shortness of breath.

If you allow too much solution to flow into the peritoneal cavity, the excess can easily be drained into the empty bag. However, overdose can result in too much body fluid and electrolyte imbalance. In this case, please consult your doctor.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using EXTRANEAL?

Things you should do

Follow the procedures and instructions from your nurse or doctor on how to carry out peritoneal dialysis with EXTRANEAL every time you do it.

EXTRANEAL dialysis solutions should be used, as prescribed by your doctor.

Body weight, blood sugar, potassium, calcium, magnesium, bicarbonate, blood protein and blood profile, as well as other indicators of your health should be monitored regularly by your doctor.

Warning for incorrect blood glucose level:

The active ingredient in EXTRANEAL can interfere with the way you measure your blood glucose. This may result in higher than true blood glucose levels being reported by your monitor. Check with your blood glucose device/monitor manufacturer to see it is safe to be used when you are on EXTRANEAL.

Call your doctor straight away if you:

- Do not feel well or develop any unwanted side effects (see section [6. Are there any side effects?](#)). Seek medical attention immediately.

Remind any doctor, surgeon, anaesthetist, dentist, pharmacist, or nurse you visit that you are using EXTRANEAL.

Things you should not do

- Do not use EXTRANEAL for intravenous administration.
- Do not heat EXTRANEAL in water or in a microwave.
- Do not stop using EXTRANEAL without letting your doctor know.

Driving or using machines

Patients on peritoneal dialysis may experience undesirable effects, which could affect the ability to drive or use machines.

Looking after your medicine

- Store below 30°C.
- Do not use after the expiry date on the bag.

Keep it where young children cannot reach it.

Follow the instructions in the carton on how to take care of your medicine properly.

When to discard your medicine

EXTRANEAL bag should be used once, and any unused portion of the solution must be discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Peritoneal dialysis procedure related disorders <ul style="list-style-type: none">• skin rash• itchy skin• pain at infusion site• hernia• discomfort	Speak to your doctor if you have any of these less serious side effects and they worry you.
Gastrointestinal disorders <ul style="list-style-type: none">• abdominal pain• Indigestion• nausea• constipation• hiccups	

<ul style="list-style-type: none"> gastritis dry mouth flatulence <p>Skin disorders</p> <ul style="list-style-type: none"> nail disorder dry skin skin discolouration skin ulcer <p>Musculoskeletal disorders</p> <ul style="list-style-type: none"> back pain fatigue increase or decrease muscle activity neck pain renal pain bone pain muscle spasm <p>Respiratory disorders</p> <ul style="list-style-type: none"> upper respiratory infection cough increase flu syndrome <p>Neurological disorders</p> <ul style="list-style-type: none"> headache dizziness confusion disturbed vision anxiety, abnormal thinking, nervousness loss of taste ringing in ears fainting 	
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<p>blood pressure, increased heart rate)</p> <p>Cardiac and vascular disorders</p> <ul style="list-style-type: none"> high blood pressure low blood pressure chest Pain <p>Musculoskeletal disorders</p> <ul style="list-style-type: none"> muscle cramps <p>Infections</p> <ul style="list-style-type: none"> peritonitis (with cloudy fluid in the drainage bag, abdominal pain, nausea and vomiting, fever, chills and, if untreated, generalised blood poisoning) <p>Respiratory disorders</p> <ul style="list-style-type: none"> shortness of breath rapid heart rate <p>Gastrointestinal disorders</p> <ul style="list-style-type: none"> vomiting diarrhoea loss of appetite blockage in bowel ulcer <p>Endocrine disorders</p> <ul style="list-style-type: none"> high blood sugar low blood sugar parathyroid disorder <p>Peritoneal dialysis procedure related disorders</p> <ul style="list-style-type: none"> catheter blockage 	
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Serious side effects

Serious side effects	What to do
<p>Peritoneal dialysis procedure related disorders</p> <ul style="list-style-type: none"> peritonitis accidental Injury exit site infection Infection <p>Renal disorders</p> <ul style="list-style-type: none"> electrolyte and fluid imbalances fluid retention (swollen feet) low blood volume low potassium high phosphate low protein symptoms of overhydration (e.g. swollen legs, shortness of breath, high blood pressure, increased body weight) symptoms of dehydration (e.g. dizziness, muscle cramps, low 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EXTRANEAL contains

Active ingredient (main ingredient)	Icodextrin, sodium chloride, sodium lactate, calcium chloride dihydrate, magnesium chloride hexahydrate
Other ingredients (inactive ingredients)	hydrochloric acid, sodium hydroxide, water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What EXTRANEAL looks like

EXTRANEAL is clear peritoneal dialysis solution. EXTRANEAL solutions are available in pack sizes of 1500 mL, 2000 mL, 2500 mL, and 3000 mL.

- Standard single bag: flexible PVC container in 1500 mL, 2000 mL, 2500 mL and 3000 mL volumes. AUST R 91344.
- Twin Bag: flexible PVC container in 1500 mL, 2000 mL, 2500 mL and 3000 mL volumes. A drainage bag is attached. AUST R 91430.

Not all pack sizes are marketed.

Who distributes EXTRANEAL

VANTIVE Pty Ltd

1 Baxter Drive

OLD TOONGABBIE NSW 2146 AUSTRALIA

This leaflet was prepared in December 2025.