
Consumer Medicine Information

1. Identification

Promit® is an aqueous (water based) solution which contains dextran 1 (a sugar like material) and sodium chloride (salt). Promit is administered intravenously (into a vein, usually in the arm) and supplied in a 20 mL single dose polypropylene ampoule which contains 3 grams of dextran 1 and 120 mg of sodium chloride dissolved in water for injection. Each 20 mL (4 teaspoonsful) ampoule is equivalent to one dose.

Australian Registration Number 80038

2. What Promit® is used for and how it works

Promit® is used to diminish the chance of patients suffering a severe allergic reaction to dextran- based fluids, such as dextran 40 or dextran 70. When given before a dose one of these fluids, Promit dramatically reduces the chance of a patient suffering a severe reaction. Promit does not completely eliminate the chance of a reaction occurring (approximately 1/ 27000). Since Promit is also a dextran containing product, there is also a small risk of an allergic reaction from this product.

Dextran 40 and dextran 70 are intravenous fluids which may be administered in large volumes (500mL) in cases of serious injury or during surgical procedures. In rare cases a patient may suffer allergic reactions to these dextran based products. Patients with an allergic sensitivity to dextran products have antibodies in their blood which can bind to dextran and form allergenic (allergic) complexes. When a sensitive patient is given Promit , the antibodies in their blood are belived to bind to the Promit instead and form inactive complexes. Because of this, if these patients are given either dextran 40 or dextran 70, there are less antibodies left in their blood to react with these dextran based fluids.

Not all patients have an allergic sensitivity to dextran based fluids. Because it is not possible to definitely identify which patients are at risk of an allergic reaction to dextran based fluids your doctor may administer Promit as a precaution before using these fluids.

3. Advice before using Promit®

Since products such as Promit are only administered in a hospital setting your doctor will decide whether you will need an injection of a dextran based solution and therefore a pre-injection of Promit.

However, Promit or any other dextran based product should not be given to patients with certain conditions and you should tell your doctor if you have ever had a reaction to a product containing dextran, have any type of:

- bleeding disorder
- take any blood thinning drugs
- have any heart or kidney disease

You should also tell your doctor if you know or believe you may be pregnant or if you are currently breast feeding.

4. How to use Promit® properly

Promit is a prescription only medical product and is only administered under a doctor's supervision in a hospital setting. Only one injection of Promit is usually required. However, if more than 48 hours (2 days) passes between doses of a large volume dextran based solution, another pre-injection of Promit is needed.

5. Further information

Promit is a prescription only medical product.

6. Unwanted effects

As with any medicinal product unwanted effects can occur. Promit can, in rare cases, cause an anaphylactic (allergic) reaction. Other unwanted effects which have been associated with the use of Promit include hypotension (low blood pressure), bradycardia (slow heart rate), broncho spasm (temporary constriction of the bronchi, an air passage in the lung), fever, vomiting, dyspnoea (breathing difficulty), flushing, coughing, rash, pruritus (itching), tachycardia (rapid heart rate) and facial oedema (facial swelling).

Your doctor is familiar with these possible unwanted effects and will carefully monitor your condition. However if you experience any unwanted effects even if it is not listed above you should tell your doctor.

7. In case of overdose

In the majority of cases only a single 20 mL dose of Promit is used under medical supervision. This is much lower than the dose of Promit safely tolerated in clinical studies, and the risk of overdose is minimal.

8. Storage conditions

The Promit you will receive will be stored by the hospital pharmacy at the temperature recommended by the manufacturer, at or below 25 deg C and will be protected from freezing. Before use the solution will be examined by your doctor or nurse for any visible signs of deterioration and the expiry date checked.

9. Where to go for further information

If you need further information on how or why Promit is used, possible unwanted effects or have any other questions you should contact your doctor, the marketing authorisation holder of the product Pharmed Australia Pty Limited (phone + 46 8 587 718 00) or the sponsor Medical Specialties Australia Pty Limited (phone 02 9417 7955).

10. Name and address of the Australian sponsor of the medicinal product

Medical Specialties Australia Pty limited,
ACN 003 624 155; ABN 75 880 043 044;
2 McCabe Place, Willoughby, NSW 2068.

11. Date of Information

7 February 2003