【成分】
注射液含有5%的乳酸林格液（乳酸氢及氯化钠溶液）及0.9%的氯化钠溶液。乳酸盐在体内可被代谢为乳酸及碳酸，以碳酸的形式与血液中的钙结合，形成游离的钙离子，有助于维持血清钙离子的正常水平。

【作用機制】
注射液中的乳酸盐在体内代谢产生的乳酸，通过影响血清钙离子的浓度，达到降低血钙的作用。乳酸盐的代谢会产生乳酸，乳酸与血液中的钙离子结合，形成碳酸钙，碳酸钙在肾脏中被排泄，从而降低血钙水平。

【用法用量】

1. 本品用于治疗高钙血症。
2. 本品可用于的患者包括：(1)近期危及生命的高钙血症；(2)需要快速降低血钙水平的患者。
3. 本品的用法用量为：一次1000ml，每10分钟静滴一次，持续约1-2小时。

【不良反应】
注射液引起的不良反应包括：(1)恶心、呕吐；(2)腹痛；(3)皮肤过敏；(4)过敏性休克。

【注意事项】
注射液的使用注意事项包括：(1)使用前应检查包装是否完整，确保无破损；(2)使用过程中应密切观察患者的反应，如出现异常应及时处理；(3)使用过程中应避免直接接触皮肤，以防过敏。

【贮藏】
本品应贮存于阴凉干燥处，避免阳光直射。

【有效期】
本品有效期为3年。

【生产厂家】
此信息未提供，需查阅具体生产厂商。

【批号】
此信息未提供，需查阅具体批号信息。
Presentation

Transdate Injection: 5 ml ampoules each containing 25 mg (5 mg/ml) labelate hydrochloride in an aqueous colourless solution. Labelate hydrochloride is 2-hydetyl-Hydroxy-2-(2-methyl-2H-1,3-benzoxazinyl)carboxylic acid benzilate.

Uses

Indications

Severe hypertension, including severe hypertension of pregnancy, when rapid control of blood pressure is essential.

- Anaesthesia when a hypotensive technique is indicated.
- Hypotensive episodes following acute myocardial infarction.

Mode of Action

Transdate lowers blood pressure by blocking peripheral histamine receptor-alpha-adrenergic, thus reducing peripheral resistance, and by concurrent beta-blockade, protects the heart from reflex sympathetic drive that would otherwise occur. Cardiac output is not significantly reduced at rest or after exercise. Increases in systolic blood pressures during exercise are corrected changes in diastolic pressure are essentially normal. All these effects would be expected to benefit hypertensive patients.

Dosage and Administration

Transdate Injection is administered for intravenous use in hospitalised patients. Patients should always receive the drug whilst in the supine or left lateral position. Raising the patient from the upright position within three hours of intravenous Transdate administration should be avoided since excessive postural hypotension may occur.

Adults

Bolus injection

It is essential to reduce the blood pressure quickly if a dose of 50 mg should be given by intravenous injection (over a period of at least one minute), and if necessary, repeated at five minute intervals until a satisfactory response occurs. The total dose should not exceed 300 mg. The maximum effect usually occurs within 5 minutes and the duration of action is usually about 8 hours but may be as long as 18 hours.

Intravenous Infusion

A fixed regime of intravenous infusion should be adopted where effective blood pressure control is required. The total dose of eight ampoules (200 mg) is said to 200 ml of Sodium Chloride and Dextrose Injection BP or 5% Dextrose Intravenous Infusion BP. Hypertension in pregnancy-infusion should be started at 20 B/min, then doubled every 30 minutes until a satisfactory response is achieved. Occasionally higher doses may be necessary. Hypotensive episodes following acute myocardial infarction-infusion should be started at 15 B/min and gradually increased to a maximum of 120 B/min depending on the control of blood pressure. Hypertension due to various causes-infusion at a rate of about 2 B/min until a satisfactory response is obtained, then stop. The effective dose is usually 50-300 mg but higher doses may be needed, especially in patients with pheochromocytoma. The rate of infusion may be adjusted at the discretion of the physician. It is desirable to monitor the blood pressure and heart rate after injection and during infusion. In most patients, there is a small increase in the heart rate; severe bradycardia is unusual but may be controlled by administering atropine 1-2 mg intravenously. Transdate has been administered to patients with various myopathies without undue hypertensive reaction.

Children

Safety and efficacy in children are not established.

Contra-indications

Transdate Injection is contra-indicated in second or third degree heart block, cardiogenic shock and other conditions associated with severe and prolonged hypertension or severe tracheology. When peripheral vasoconstriction shows low cardiac output, the use of Transdate Injection to control hypertensive emergencies is contra-indicated. Labelate is contra-indicated for patients with asthma or a history of obstructive airway disease unless no alternative treatment is available. In such cases, the risk of histamine release seems too great.

Precautions

When cardiac reserves are poor, control by a cardiac glycoside or a dibenzylamine should be obtained prior to the cautious use of Transdate Injection. Transdate injection need not be discontinued but patients should be observed closely and titrated to the minimum effect. Beta-blockers, even those with added cardiac activity, should not be used in patients with asthma or a history of obstructive airways disease unless no alternative treatment is available. In such cases, the risk of histamine release seems too great.

Pregnancy and Lactation

Although no teratogenic effects have been demonstrated in animals, Transdate should only be used during the first trimester of pregnancy if the potential benefits outweigh the possible risks. Transdate Injection is not recommended for use in lactation, but patients should be observed closely and titrated to the minimum effective dose. Transdate Injection may be used in pregnant women if they are being treated with other drugs that may mask the compensatory physiological responses of t turbulent haemorraghic stroke. Close attention must therefore be paid to blood loss and the blood volume maintained.

Side effects

Transdate Injection is usually well tolerated. Pronounced postural hypotension may occur if patients are allowed to assume the upright position within three hours of receiving Transdate Injection. Rare reports of rash, pruritus, angioneurotic edema and dyspnea. A few reports of peripheral neuropathy. There are no contraindications, but patients who are allergic to benzilate and/or its components should avoid this drug.

Overdosage

Ritin (Pharmacist) over 50 mg intravenously has caused a fall in blood pressure, but no other effects were noted. In cases of anaphylactic shock, epinephrine should be given. If severe hypotension develops, Transdate Injection should be discontinued and supportive measures taken. Treatment of severe hypotension includes fluid therapy and measures to maintain electrolyte balance. Further treatment is supportive and includes fluid therapy and measures to maintain electrolyte balance. Further treatment is supportive and includes fluid therapy and measures to maintain electrolyte balance.

Compatibility

Transdate Injection is compatible with the following intravenous infusions: 5% Dextrose BP, 0.16% Sodium Chloride and 4% Dextrose 0.33% Sodium Chloride Injection BP. Compound Sodium Lactate BP. Unusual admixtures should be discarded 24 hours after preparation. Transdate injection has been shown to be incompatible with Sodium Bicarbonate injection BP (4.2 w/v).

Pharmacokinetics

The plasma half-life of labelate is about four hours. About 50% of labelate in the blood is protein bound. Labelate is metabolised mainly through conjugation to tricunvaline and then via uric acid and in the urine. There are excreted in the urine both in the urine and via the bile, to the faeces. Only negligible amounts of the drug cross the blood brain barrier in animal studies.

Further information

Transdate does not adversely affect renal function and is particularly suitable for use in hypertensive patients with renal disease. Transdate fluorochrome and a fixed regime of intravenous infusion at 20 B/min for 30 minutes, with a concentration of 0.25 mg/ml to 0.5 mg/ml and a concentration of 0.5 mg/ml and a concentration of 1 mg/ml, can be used for patients with severe hypertension and compensated cardiovascular disease. The presence of labelate in the urine may result in falsely elevated levels of uric acid and may cause gout. Labelate is not dialysable and is not removed by hemodialysis or peritoneal dialysis. In these patients, however, gout is less likely to occur when labelate is used. Labelate has been shown to be effective in the treatment of hypertensive patients with a history of gout. Labelate is not dialysable and is not removed by hemodialysis or peritoneal dialysis. In these patients, however, gout is less likely to occur when labelate is used. Labelate has been shown to be effective in the treatment of hypertensive patients with a history of gout.

Package quantities

5 ml ampoules, boxes of 5