

Alprostadil IV for Severe Raynaud’s phenomena complicated by digital ischemia or ulceration (Prostaglandin E1 (PGE1))



Areas where Protocol/Guideline applicable	Prostaglandin E1 is a potent vasodilator and inhibitor of platelet aggregation and has been used in success in severe Raynaud’s phenomena complicated by digital ischemia or ulceration. This medication can be delivered in a general ward such as CAU (Prince of Wales Hospital).
Authorised Prescribers:	Medical officer, provided patient has had consultation alongside the rheumatology or vascular surgery department
Indication for use	Severe Raynaud’s phenomena complicated by digital ischemia or ulceration
Clinical condition	Severe Raynaud’s phenomena complicated by digital ischaemia or ulceration. This includes but is not limited to patients with systemic sclerosis.
Proposed Place in Therapy	First line (at the discretion of the Rheumatologist) for severe Raynaud’s phenomena complicated by digital ischemia or ulceration
Adjunctive Therapy	Nil
Contra-indications	Congestive heart failure secondary to severe left ventricular dysfunction Pulmonary oedema secondary to initial Alprostadil use Hypersensitivity to Alprostadil Pregnancy Breastfeeding
Precautions	Primary pulmonary hypertension Coronary artery disease Rapid decrement in infusion rate, abrupt withdrawal, interruption in drug delivery (in patients with pulmonary arterial hypertension) Extravasation Ascites risk including right heart failure, chronic congestive hepatopathy Monitor heart rate and blood pressure Bleeding risk Elderly > 65 yrs; lactation; children
Important Drug Interactions	Antihypertensives Vasodilators Drugs affecting platelet aggregation Anticoagulants Digoxin Tissue plasminogen activator
Dosage	Please see table below (weight-based schedule)
Duration of therapy	Patient will receive a continuous infusion for 72 hours at the maximum tolerated flow rate
Prescribing Instructions	Obtain patient consent. Alprostadil must be prescribed on the eMR (eFluids) with administration rates clearly specified. In eRIC the rate of alprostadil must be prescribed in mL/hour. In the absence of eMM systems, the appropriate paper medication chart may be used.

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<p>Administration Instructions</p>	<p>This infusion should be run on ward with sufficient nursing support to perform regular observations and monitoring as stipulated below.</p> <p>Presentation: Alprostadil PGE1 (Prostin VR) Supplied as sterile solution of 500microg in 1mL of alcohol (0.5mg/mL) Preparation: Add 1 vial of 500microg/mL alprostadil to 500mL sodium chloride 0.9% or dextrose 5% in water (concentration = 1microg/mL) Prepared infusion should be stored at 4 to 8 degrees Celsius and used within 24 hours. All solution more than 24 hours old must be discarded.</p> <p>Administration:</p> <ol style="list-style-type: none"> 1. Patient requires either a PICC or CVC for administration 2. Weigh the patient (in kg) 3. Prepare the solution as outlined above. Use aseptic technique throughout the preparation 4. Administer using Infusion pump and giving sets using the weight-based rates shown below. Continue to increase rates using the table below to the maximum tolerated rates. 5. Patient will receive a continuous infusion for 72 hours at the maximum tolerated flow rate <p style="text-align: center;">Infusion volume rate (mL/hour) <u>Concentration 1 microg / mL</u></p> <table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th rowspan="2">Infusion time</th> <th colspan="7">Weight</th> </tr> <tr> <th>35-45kg</th> <th>45-55kg</th> <th>55-65kg</th> <th>65-75kg</th> <th>75-85kg</th> <th>85-100kg</th> <th>>100kg</th> </tr> </thead> <tbody> <tr> <td>0-30 minutes</td> <td>4mL/hr for 2mL then increase to</td> <td>6mL/hr for 3mL then increase to</td> <td>7mL/hr for 3.5mL then increase to</td> <td>8mL/hr for 4mL then increase to</td> <td>10mL/hr for 5mL then increase to</td> <td>11mL/hr for 5.5mL then increase to</td> <td>12mL/hr for 6mL then increase to</td> </tr> <tr> <td>30-60 minutes</td> <td>9mL/hr for 4.5mL then increase to</td> <td>12mL/hr for 6mL then increase to</td> <td>14mL/hr for 7mL then increase to</td> <td>17mL/hr for 8.5mL then increase to</td> <td>19mL/hr for 9.5mL then increase to</td> <td>22mL/hr for 11mL then increase to</td> <td>24mL/hr for 12mL then increase to</td> </tr> <tr> <td>1 hr to 7 hrs</td> <td>14mL/hr for 84mL then increase to</td> <td>18mL/hr for 108mL then increase to</td> <td>22mL/hr for 132mL then increase to</td> <td>25mL/hr for 150mL then increase to</td> <td>29mL/hr for 174mL then increase to</td> <td>32mL/hr for 192mL then increase to</td> <td>36mL/hr for 216mL then increase to</td> </tr> <tr> <td>7hr to 13 hrs</td> <td>19mL/hr for 114mL then increase to</td> <td>24mL/hr for 144mL then increase to</td> <td>29mL/hr for 174mL then increase to</td> <td>34mL/hr for 204mL then increase to</td> <td>38mL/hr for 228mL then increase to</td> <td>43mL/hr for 258mL then increase to</td> <td>48mL/hr for 288mL then increase to</td> </tr> <tr> <td>13 hrs to end</td> <td>24mL/hr for remainder of infusion</td> <td>30mL/hr for remainder of infusion</td> <td>36mL/hr for remainder of infusion</td> <td>42mL/hr for remainder of infusion</td> <td>48mL/hr for remainder of infusion</td> <td>54mL/hr for remainder of infusion</td> <td>60mL/hr for remainder of infusion</td> </tr> </tbody> </table>	Infusion time	Weight							35-45kg	45-55kg	55-65kg	65-75kg	75-85kg	85-100kg	>100kg	0-30 minutes	4mL/hr for 2mL then increase to	6mL/hr for 3mL then increase to	7mL/hr for 3.5mL then increase to	8mL/hr for 4mL then increase to	10mL/hr for 5mL then increase to	11mL/hr for 5.5mL then increase to	12mL/hr for 6mL then increase to	30-60 minutes	9mL/hr for 4.5mL then increase to	12mL/hr for 6mL then increase to	14mL/hr for 7mL then increase to	17mL/hr for 8.5mL then increase to	19mL/hr for 9.5mL then increase to	22mL/hr for 11mL then increase to	24mL/hr for 12mL then increase to	1 hr to 7 hrs	14mL/hr for 84mL then increase to	18mL/hr for 108mL then increase to	22mL/hr for 132mL then increase to	25mL/hr for 150mL then increase to	29mL/hr for 174mL then increase to	32mL/hr for 192mL then increase to	36mL/hr for 216mL then increase to	7hr to 13 hrs	19mL/hr for 114mL then increase to	24mL/hr for 144mL then increase to	29mL/hr for 174mL then increase to	34mL/hr for 204mL then increase to	38mL/hr for 228mL then increase to	43mL/hr for 258mL then increase to	48mL/hr for 288mL then increase to	13 hrs to end	24mL/hr for remainder of infusion	30mL/hr for remainder of infusion	36mL/hr for remainder of infusion	42mL/hr for remainder of infusion	48mL/hr for remainder of infusion	54mL/hr for remainder of infusion	60mL/hr for remainder of infusion
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<p>Adverse effects</p>	<p>Flushing, headache, nausea, abdominal cramps, fever</p>																																																							

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<p>Monitoring requirements</p> <p>Safety</p> <p>Effectiveness (state objective criteria)</p>	<p>Observations</p> <ul style="list-style-type: none"> Blood pressure, heart rate, respiratory rate, temperature should be recorded on admission, pre-infusion and every 15 minutes for first hour and then hourly for the next 6 hours and then every 4 hours if stable.
<p>Management of Complications</p>	<ul style="list-style-type: none"> If heart rate increases by more than 20 beats/min or blood pressure falls by more than 20mm/Hg or intolerance (flushing, headache, nausea, abdominal cramps, fever) occurs, reduce the infusion rate to the last well tolerated rate. Re-increase dose only if observations remain stable If blood pressure falls, heart rate increase, or temperature rises significantly cease the infusion and call the medical officer <p>If patient develops any serious adverse event cease infusion immediately and call the medical officer.</p>
<p>Basis of Protocol/Guideline: (including sources of evidence, references)</p>	<ol style="list-style-type: none"> RPA Hospital Rheumatology Handbook and Protocols (Updated Jan 2023). eMIMS (revision date 01 June 2025). Contraindications, drug interactions and precautions based on related medication, Veletri (Epoprostenol). https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022260s005lbl.pdf Mohrland JS, Porter JM, Smith EA, Belch J, Simms MH. A multiclinic, placebo-controlled, double-blind study of prostaglandin E1 in Raynaud's syndrome. Ann Rheum Dis. 1985 Nov;44(11):754-60. doi: 10.1136/ard.44.11.754. PMID: 3904643; PMCID: PMC1001768.(original protocol). Marasini B, Massarotti M, Bottasso B, Coppola R, Del Papa N, Maglione W, Comina DP, Maioli C. Comparison between iloprost and alprostadil in the treatment of Raynaud's phenomenon. Scand J Rheumatol. 2004;33(4):253-6. doi: 10.1080/03009740310004711. PMID: 15370722. (evidence for efficacy of alprostadil and comparability with Iloprost) Martin MF, Dowd PM, Ring EF, Cooke ED, Dieppe PA, Kirby JD. Prostaglandin E1 infusions for vascular insufficiency in progressive systemic sclerosis. Ann Rheum Dis. 1981 Aug;40(4):350-4. doi: 10.1136/ard.40.4.350. PMID: 7259326; MCID: PMC1000727. (evidence for efficacy of alprostadil based on the current protocol)
<p>Groups consulted in development of this guideline</p>	<p>Rheumatology Department, POWH Rheumatology Department, St George Hospital Pharmacy Department, POWH Pharmacy Department, St George Hospital</p>



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GOVERNANCE	
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Chairperson, DTC	Dr John Shephard
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