

*Veletri is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Veletri patient enrollment forms

Patient name:

Instructions

- 1 Review Veletri indication and important safety information on page 2
- 2 Complete patient enrollment
- 3 Document PAH* diagnosis
- 4 Determine PAH* clinical status
- 5 Complete CCB trial
- 6 Provide required documentation: right heart catheterization, echocardiogram results, and history and physical notes
- 7 Fax completed forms to **1-800-711-3526**

Reminder: Please include photocopy of both sides of patient insurance card.

Please see accompanying full prescribing information for Veletri.

VELETRI[®]
epoprostenol for Injection



This resource was created and funded by Actelion Pharmaceuticals US, Inc.

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Veletri is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Important Safety Information: Veletri is contraindicated in patients with congestive heart failure due to severe left ventricular systolic dysfunction, in patients who develop pulmonary edema during dose initiation, and in patients who have known hypersensitivity to the drug or to structurally related compounds.

Veletri should be used only by clinicians experienced in the diagnosis and treatment of pulmonary hypertension after establishing the diagnosis of idiopathic or heritable PAH or PAH/CTD.

Reconstitute Veletri only as directed using Sterile Water for Injection, USP, or Sodium Chloride 0.9% Injection, USP. Do not mix Veletri with any other parenteral medications or solutions prior to or during administration. Do not abruptly lower the dose or withdraw dosing. All dosing initiation and changes should be closely monitored.

The most common and dose-limiting adverse events during dose initiation and escalation were nausea, vomiting, headache, hypotension, flushing, chest pain, anxiety, dizziness, bradycardia, dyspnea, abdominal pain, musculoskeletal pain, and tachycardia. The most common adverse events during chronic administration were headache, jaw pain, flushing, diarrhea, nausea and vomiting, flu-like symptoms, and anxiety/nervousness. Potential adverse events from postmarketing evaluations include anemia, hypersplenism, pancytopenia, splenomegaly, and hyperthyroidism.

Additional reductions in blood pressure may occur when Veletri is administered with diuretics, antihypertensive agents, or other vasodilators. There is the potential for Veletri to increase the risk of bleeding when administered with antiplatelet agents or anticoagulants. Patients on digoxin who receive Veletri may show elevations of digoxin concentration, which may be clinically significant in patients prone to digoxin toxicity.

Please see accompanying full prescribing information for Veletri.

Fax cover sheet

To: Accredo PAH* Team

Fax number: 1-800-711-3526

Date/time: _____

From: _____

Fax number: _____

Number of pages (including this one): _____

Comments:

Checklist

- 1) Review Veletri indication and important safety information on page 2
- 2) Complete patient enrollment
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Fax completed forms to:

1-800-711-3526

For more information, call Accredo PAH*

Team: **1-866-FIGHT-PH**

1-866-344-4874

Submission of the Veletri enrollment form is not a guarantee of patient approval.

Additional testing and clinical information may be requested in some cases, including:

- ANA results
- PFTs
- V/Q perfusion scan
- Chest CT

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1

Complete patient prescription and enrollment form

accredo®



Fax to: 1-800-711-3526

Referral date: _____

New patient

Current

Prescription	Veletri (continuous IV infusion administered via ambulatory pump) Dosing weight: _____ lbs kg Height: _____ in cm NKDA Known drug allergies: _____ Diabetic: Yes No Initial dose: _____ ng per kg per min Titrate by _____ ng per kg per min every _____ days until goal of _____ ng per kg per min is reached. Discharge dose: _____ ng per kg per min Concentration: _____ ng/mL Dispense two (2) ambulatory infusion pumps appropriate for Veletri if the patient does not currently have appropriate ambulatory infusion pumps. Refills: 1 2 3 4 5 6 7 8 9 10 11 Patients should keep at least a 7-day backup supply of medication and supplies at all times.		Ship-to directions: Physician office Patient's home Hospital	
	Address (no PO Box): _____		City: _____	
	State: _____ Zip: _____		Ship Attn: _____	
	Quantity: Dispense 1 month of drug and supplies, including pump(s) Choose one: Sterile water for injection Sodium chloride 0.9% injection			
	I certify that I am prescribing Veletri for this patient as a medically appropriate treatment. By signing, I certify that the therapy is medically necessary and that I authorize the designated specialty pharmacy to be my designated agent to (1) provide any information on this form to the insurer of the named patient and (2) to forward the prescription by fax or other mode of delivery to the designated specialty pharmacy. This Appointment and Authorization shall be in force until cancelled in writing by the prescribing physician. Prescriber's printed name: _____ Date: _____ Prescriber signature: _____ (Physician attests this is his/her legal signature. NO STAMPS)			

Choose one: Urgent: Patient in hospital Emergent: Admission after 48-72 hours Standard: Admission within 4+ days

Start-of-care date (REQUIRED): _____ **Tentative discharge date:** _____

Nursing services requested to be provided by Accredo staff (Check all that apply):

- In-hospital training (Accredo)
 Postdischarge visit/in-home follow-up
 Home assessment/training prior to initiation of therapy
 Dispense teaching kits
 DECLINE: All referenced nursing

If nursing services will be required for therapy administration, the home health nurse will call for additional orders per state regulations.

Discharge planner/coordinator name _____

Date _____ Time _____ Fax # _____ Office/page phone# _____

REQUIRED: PLEASE PROVIDE COPIES OF PATIENT'S CURRENT MEDICAL INSURANCE AND PRESCRIPTION CARDS.

Physician Information	All fields must be completed to expedite prescription fulfillment.					
	Name:		DEA # (optional):		NPI #:	
	Name of facility:		MD specialty:		UPIN #:	
	Contact name and phone #:		State license #:		Phone #:	
	Address: Suite:		City:		State:	Zip:
	Referral source: (Check one) Prescribing physician Patient self-referral No referring MD		PCP (if applicable/different from prescribing MD) _____ Phone _____			

Patient Information	Name:		SSN:		DOB:	
	Address:		City:		State:	Zip:
	Preferred language, if not English:			Phone #:		Sex: Male Female
	Parent/guardian (if applicable):			Employer:		Alternate phone #:
	May we contact the patient regarding insurance benefits and product delivery? Yes No					

Insurance Information	Primary insurance company:				Phone #:	
	Policy holder name:		SSN:		DOB:	
	Relationship to patient:		Insured employer:		ID #:	
	Secondary insurance company:				Phone #:	
	Policy holder name:		SSN:		DOB:	
	Relationship to patient:		Insured employer:		ID #:	
	Drug card company:		Phone #:		ID #:	
	Rx BIN #:		PCN #:		Person code:	

Please see page 2 for indication and accompanying full prescribing information for Veletri.

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2 | Document diagnosis

Fax to: 1-800-711-3526

Patient: _____ DOB: _____

Physician: _____

It is the responsibility of the Prescriber to complete this form with information that most accurately and completely describes the condition of the patient, regardless of the potential impact on insurance coverage or reimbursement. Actelion makes no representation that the diagnosis information printed on this form is accurate or complete or that it will support insurance coverage or reimbursement.

Please select the diagnosis information that most accurately and completely describes the signs, symptoms, and condition of the patient:

WHO GROUP 1 PAH* DIAGNOSES

ICD-9: 416.0 Primary Pulmonary Arterial Hypertension (Idiopathic PAH*)

ICD-9: 416.0 Familial Pulmonary Arterial Hypertension (FPAH)

ICD-9: 416.8 Secondary Pulmonary Hypertension (Associated PAH*)

Please specify one:

Connective Tissue Disease (eg, CREST, MCTD, Scleroderma, Lupus)

Other: _____

OTHER

ICD-9: _____ Description: _____

MEDICAL RATIONALE FOR OTHER

Prescriber signature: _____ **Date:** _____

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3 Determine clinical status

Fax to: 1-800-711-3526

Patient: _____ DOB: _____

Physician: _____

NYHA functional class: (Check only one)

Class III

Class IV

Other: _____

Clinical signs and symptoms: (Check all appropriate)

Fatigue

Shortness of breath or dyspnea on exertion

6-minute walk: _____ meters Date of evaluation: _____

Chest pain or pressure (angina)

Syncope or near syncope

Increasing limitation of physical activity

Other: _____

Course of illness: (Check all appropriate)

Evidence of worsening heart failure (eg, rales on physical exam, worsening edema, increased NT-proBNP, increased CRP)

Worsening pulmonary hemodynamics (eg, mPAP, RAP, PVR, CO)

Decreasing 6-minute walk test

Change in functional class

Worsening dyspnea on exertion

Change in patient-reported symptoms (eg, increased fatigue)

Other: _____

Prescriber signature: _____

Date: _____

Please see accompanying full prescribing information for Veletri.

4 | Complete calcium channel blocker trial

Fax to: 1-800-711-3526

Patient: _____ DOB: _____

Physician: _____

Prior to the initiation of Veletri, Medicare policy requires documentation that a calcium channel blocker (CCB) has been tried, failed, or considered and ruled out. Because many PAH* patients may become disabled and Medicare eligible, the following documentation is generally required prior to initiation of treatment with Veletri.

The above named patient was trialed as follows:

A CCB was not trialed because:

Patient did not meet ACCP Guidelines¹ for Vasodilator Response (ie, a fall in mPAP ≥ 10 mm Hg to ≤ 40 mm Hg, with an unchanged or increased cardiac output)

Patient is hemodynamically unstable or has history of postural hypotension

Patient has systemic hypotension (SBP ≤ 90 mm Hg)

Patient has depressed cardiac output (cardiac index ≤ 2.4 L/min/m²)

Patient has known hypersensitivity

Patient has documented bradycardia or second- or third-degree heart block

Other: _____

OR

The following CCB was trialed:

CCB: _____

With the following response:

Pulmonary arterial pressure continued to rise

Disease continued to progress or patient remained symptomatic

Patient hypersensitive or allergic

Adverse event: _____

Patient became hemodynamically unstable

Other: _____

Prescriber signature: _____ **Date:** _____

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Reference: 1. Badesch DB, Abman SH, Simonneau G, Rubin LJ, McLaughlin VV. Medical therapy for pulmonary arterial hypertension: updated ACCP evidence-based clinical practice guidelines. *Chest*. 2007;131:1917-1928.

5 | Provide required documentation

Patient: _____ DOB: _____

Physician: _____

Please check each box once completed.

Right heart catheterization has been performed. Results form is attached.

The right heart catheterization report should include:

- Mean pulmonary artery pressure (or systolic and diastolic pressure)
- Cardiac output (CO)
- Pulmonary vascular resistance (PVR)
- Pulmonary capillary wedge pressure (or LVEDP)

Echocardiogram has been performed to rule out left-sided heart or valvular disease. Results form is attached.

Current history and physical notes with need for therapy and PAH* symptoms (ie, dyspnea on exertion, and either fatigue, angina, or syncope) documented. Notes are attached.

Prescriber Initials: _____ Date: _____

Sample right heart catheterization results form

PPH Hemodynamic DATA COLLECTION SHEET							
Acute Study - Cardiac Catheterization Lab							
Patient Name: _____	M.R.# _____		Date: _____				
Ht. _____ cm	Wt. _____ kg	BSA _____					
Physician: _____	Title: _____		Age: _____				
Procedure: R-CPPH	Tab: _____		Rhythm: _____				
Time Measured	Baseline	Stim/Tab	Exercise	End Ex	Post 1	Post 2	Baseline
Heart Rate							
Body Temp							
Resp. rate							
FiO2 %							
SaO2 %							
RV							
PA cath							
PA wedge							
AO cath							
AO mean							
CVP							
ml CO x1							
ml SVR x1							
PVR/PVRI dist							
TPR							
PVR w/out							
Stroke Vol. index							
Heart rate							
Heart rate							
PAw Sat %							
RA Sat %							
RV Sat %							
SV Sat %							
RV Sat %							
PAN O2 Sat							
Art Sat Sat							
BSA							

Sample echocardiogram results form

Echocardiogram Report	
Patient: _____	Age: _____
Procedure Date: _____	ID #: _____
Referring Physician: _____	Clinic ID: _____
Reviewing Physician: _____	Procedure: _____
Technician: _____	Tape Number: _____
	Echo Chart: _____
Indication:	
Measurements: (Normal in Parentheses)	
Estimated Ejection Fraction: _____ (55-75%)	
Left Ventricular Dimensions:	
End diastole: _____ cm	Septal wall: _____ cm (0.6 - 1.1 cm)
End systole: _____ cm	Posterior wall: _____ cm (0.6 - 1.1 cm)
Right Ventricular Dimensions	
End diastole: _____ cm	Lateral wall: _____ cm
End systole: _____ cm	
Aorta: _____ cm (2.0 - 3.7 cm)	Left Atrium: _____ cm (1.9 - 4.0 cm)
Hemodynamics:	
Pulmonary acceleration time	_____ msec
Systolic right ventricular pressure (estimated):	_____
Diastolic pulmonary pressure (estimated):	_____ msec
Mitral inflow deceleration time	_____ msec
Pulmonary vein "A" wave duration	_____ msec
Pulmonary vein "A" wave velocity:	_____ msec
Mitral inflow "A" wave duration	_____ msec
TR jet velocity	_____ m/sec
Findings:	
Conclusions:	

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