



# Supply Disruption Alert

SDA/2021/015

Issued: 25 November 2021

## Hypovase<sup>®</sup> (prazosin) 500microgram tablets – Supply Disruption

### Summary

- Hypovase<sup>®</sup> (prazosin) 500 microgram tablets will be out of stock from late November 2021 until mid-January 2022. Pfizer are the sole supplier of prazosin 500 microgram tablets in the UK.
- Prescribers will need to review all affected patients to discuss management plans.
- Alternative alpha blockers remain available and can support an uplift in demand.
- Unlicensed supplies of prazosin 500microgram tablets have been sourced and may be considered where the above option is inappropriate.

### Action

All healthcare professionals in primary, secondary or specialist healthcare services who prescribe or supply Hypovase<sup>®</sup> (prazosin) 500 microgram tablets should be aware of the following advice:

Clinicians should:

- defer initiating new patients on Hypovase<sup>®</sup> (prazosin) 500 microgram tablets until the supply disruption is resolved;
- identify patients with insufficient supplies to last until the resupply date and:
  - refer to local or national treatment guidelines to switch to an alternative medication for licensed indications (see advice section below); or
  - make early contact with secondary/tertiary care specialists for advice and/or referral where Hypovase<sup>®</sup> (prazosin) 500 microgram tablets are used off-label, for example in Post-Traumatic Stress Disorder (PTSD).
- only consider prescribing unlicensed supplies of prazosin 500microgram tablets where the alternative options are considered inappropriate (see advice below - prescribers should work with local pharmacy teams to ensure orders are placed within appropriate timeframes as lead times may vary);
- monitor patients for changes in blood pressure and/or symptom control if prescribing alternative medications;
- counsel patients on new dose regime and potential side-effects if prescribing alternative medications; and
- review and discuss appropriate next steps and management with the patient when licensed Hypovase<sup>®</sup> (prazosin) 500 microgram tablets are resupplied.

### Product details

Hypovase<sup>®</sup> (prazosin) 500 microgram tablets (Pfizer)

## Background

Pfizer are out of stock of Hypovase<sup>®</sup> (prazosin) 500 microgram tablets from late November 2021 until mid-January 2022 due to a manufacturing issue.

Hypovase<sup>®</sup> (prazosin) 1mg tablets were discontinued by Pfizer in May 2021.

## Alpha blockers place in treatment

### Hypertension and Benign Prostatic Hypertension

[NICE guideline for hypertension](#) suggests that for people with confirmed resistant hypertension (i.e. despite optimal tolerated doses of an ACE inhibitor or an angiotensin II receptor blocker plus a calcium channel blocker and a thiazide-like diuretic), consider adding a fourth antihypertensive drug as step 4 treatment, of which alpha-blockers are a treatment option.

[NICE guideline for lower urinary tract symptoms in men](#) suggests that an alpha blocker (alfuzosin, doxazosin, tamsulosin or terazosin) may be offered to men with moderate to severe lower urinary tract symptoms.

See Table 1 for more information.

### Congestive Heart Failure and Raynaud's disease

Although prazosin is also licensed for treating congestive heart failure and Raynaud's disease, alpha blockers do not feature in heart failure guidelines and prazosin is not considered clinically effective for Raynaud's Disease.

## Advice on switching patients to alternative treatments

Prazosin is licensed for hypertension, benign prostatic hyperplasia, congestive heart failure and Raynaud's disease.

### Off-label uses

Prazosin is used off-label to treat nightmares and sleep disturbance associated with post-traumatic stress disorder (PTSD) in a limited number of patients under specialist Mental Health services. Any patients using Hypovase<sup>®</sup> (prazosin) 500 microgram tablets for PTSD should be reviewed by their Specialist Mental Health Team.

### Alternative alpha blockers for licensed indications

There are alternative alpha blockers that remain available and can support an increase in demand during this time.

There is no direct dose conversion data so treatment with an alternative alpha blocker should be titrated according to the patient's clinical response. Refer to dosing advice in the BNF, SmPC's or Clinical Knowledge Summary (CKS).

Table 1

Licensed indication	Alpha blocker	BNF dose range
Hypertension	Doxazosin immediate release	1mg to 16mg daily
	Doxazosin modified release	4mg to 8mg once daily
	Terazosin	1mg to 10mg daily
Benign Prostatic Hyperplasia	Doxazosin immediate release	1mg to 8mg daily
	Doxazosin modified release	4mg to 8mg once daily
	Terazosin	1mg to 10mg daily
	Tamsulosin modified release	400 micrograms once daily
	Alfuzosin immediate release	2.5mg two to three times daily; maximum 10mg daily
	Alfuzosin modified release	10mg once daily

- [SmPC doxazosin tablets](#)
- [SmPC terazosin tablets](#)
- [SmPC tamsulosin 400 microgram modified release capsules and tablets](#)
- [SmPC alfuzosin tablets](#)
- [CKS Hypertension: Alpha-blockers](#)
- [CKS Lower urinary tract symptoms \(LUTS\) in men: Alpha-blockers](#)

## Unlicensed imports

The following specialist importer(s) have confirmed they can source unlicensed prazosin 500 microgram tablets (please note, there may be other companies that can also source supplies):

- Alium Medical
- Mawdsley's Unlicensed

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:

- [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency
- [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
- [Prescribing unlicensed medicines](#), General Medical Council (GMC)

## Distribution

### Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E nurses
- All departments
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Cardiothoracic departments
- Chief pharmacists
- Clinical governance leads

- Clinical Procurement Specialists
- Community hospitals
- Community nurses
- Day surgery units
- District nurses
- EBME departments
- Emergency Preparedness and Response officer
- Equipment stores
- Equipment libraries and stores
- General Practice
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff
- Intensive care nursing staff (adult)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Mental Health Trusts
- NHS walk-in centres
- Occupation health departments
- Outpatient clinics
- Palliative care teams
- Paramedics
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Risk managers
- Supplies managers
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Walk-in centres

### **NHS England regional teams**

For onward distribution to all relevant staff including:

- Community Pharmacists

### **General Practice**

For onward distribution to all relevant staff including:

- General practitioners
- General practice managers
- General practice nurses
- Non-medical prescribers in General Practice

### **Independent distribution**

#### **Establishments registered with the Care Quality Commission (CQC) (England only)**

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

## **Enquiries**

Send enquiries about this notice to the DHSC Medicines Supply Team, quoting reference number SDA/2021/015

Email: [DHSCmedicinesupplyteam@dhsc.gov.uk](mailto:DHSCmedicinesupplyteam@dhsc.gov.uk)