

29 February 2024

Dear Healthcare Professional,

Shortage of ALPHAPRESS 50 hydralazine hydrochloride 50mg tablet bottle (AUST R: 60380) and ALPHAPRESS 25 hydralazine hydrochloride 25mg tablet bottle (AUST R: 17575) and alternate supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.

The above Australian registered medicines are in shortage due to manufacturing issues.

Medsurge has been able to arrange for the supply of HydrALAZINE Hydrochloride Tablets, USP 25mg (Camber USA) and HydrALAZINE Hydrochloride Tablets, USP 50mg (Camber USA) as alternative products on a temporary basis. These products are NOT registered in Australia, and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **30 June 2024** for the following indications:

Hypertension (drug resistant, moderate to severe):

As supplementary medication for use together with other antihypertensives such as beta-blockers and diuretics; the complementary mechanisms of action of such combined therapy enable the drugs to exert their antihypertensive effects at low doses; in addition, unwanted accompanying effects of the individual substances are either partially offset or even cancelled out.

HydrALAZINE Hydrochloride Tablets, USP 25mg (Camber USA) and HydrALAZINE Hydrochloride Tablets, USP 50mg (Camber USA) are identical in active ingredient and strength to the Australian registered products. HydrALAZINE Hydrochloride Tablets, USP 25mg (Camber USA) and HydrALAZINE Hydrochloride Tablets, USP 50mg (Camber USA) are registered and marketed in USA by Camber Pharmaceuticals, Inc & therefore all the labelling is in English.

A comparison table of differences between Australian registered products ALPHAPRESS 50 hydralazine hydrochloride 50mg tablet bottle (AUST R: 60380), ALPHAPRESS 25 hydralazine hydrochloride 25mg tablet bottle (AUST R: 17575) and the section 19A products HydrALAZINE Hydrochloride Tablets, USP 25mg (Camber USA) and HydrALAZINE Hydrochloride Tablets, USP 50mg (Camber USA) is given below:

	ARTG product ALPHAPRESS 50 hydralazine hydrochloride 50mg tablet bottle (AUST R: 60380) ALPHAPRESS 25 hydralazine hydrochloride 25mg tablet bottle (AUST R: 17575)	S19A Product HydrALAZINE Hydrochloride Tablets, USP 50mg (Camber USA) HydrALAZINE Hydrochloride Tablets, USP 25mg (Camber USA)
Excipients	<ul style="list-style-type: none"> colloidal anhydrous silica, 	<ul style="list-style-type: none"> Anhydrous lactose

	<ul style="list-style-type: none"> • disodium edetate, • magnesium stearate, • pregelatinized maize starch, • purified talc, • sodium starch glycolate • microcrystalline cellulose • Opadry Pink OY-LS-34902 (Proprietary Ingredient Number: 2948) (50mg tablets only) • Lactose monohydrate (50mg tablets only) 	<ul style="list-style-type: none"> • Stearic acid • FD&C Yellow No.6 • Sodium starch glycolate Type A potato • microcrystalline cellulose
Pack Size	Bottles of 100 tablets	Bottles of 100 tablets.
Storage	Store below 25°C. Protect from light.	Store at 20°-25°C.

Please refer to Australian Product Information for **ALPHAPRESS 50 hydralazine hydrochloride 50mg tablet bottle (AUST R: 60380)** and **ALPHAPRESS 25 hydralazine hydrochloride 25mg tablet bottle (AUST R: 17575)** available here: www.ebs.tga.gov.au when prescribing or administering **HydrALAZINE Hydrochloride Tablets, USP 25mg (Camber USA)** and **HydrALAZINE Hydrochloride Tablets, USP 50mg (Camber USA)**.

Any adverse events which are experienced with **HydrALAZINE Hydrochloride Tablets, USP 25mg (Camber USA)** and **HydrALAZINE Hydrochloride Tablets, USP 50mg (Camber USA)** should be reported by healthcare professionals to Medsurge on 1300 788 261 or email sales@medsurge.com.au. Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Any product complaints with **HydrALAZINE Hydrochloride Tablets, USP 25mg (Camber USA)** and **HydrALAZINE Hydrochloride Tablets, USP 50mg (Camber USA)** should be reported to Medsurge on 1300 788 261 or email sales@medsurge.com.au.

Please forward this information to relevant staff members in your organisation.

For further information, please contact Medsurge Healthcare on 1300 788 261 or by email sales@medsurge.com.au.

Kind regards,

Ramya.H.Gowda

Senior Regulatory Affairs

Medsurge Healthcare