17th January 2024

Dear Healthcare Professional,

Shortage of VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle (AUST R: 199226), VYVANSE lisdexamfetamine dimesilate 60 mg capsules bottle (AUST R: 284021) 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 VYVANSE lisdexamfetamine dimesylate capsules 50mg (USA) and VYVANSE lisdexamfetamine dimesylate capsules 60mg (USA) as alternative products on a temporary basis. These product 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:

> *Attention Deficit Hyperactivity Disorder (ADHD)*
> *It is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Treatment should be commenced by a specialist.*
> *A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before 12 years of age.*
>
> *Binge Eating Disorder (BED)*
> *It is indicated for the treatment of moderate to severe BED in adults when nonpharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist.*

Healthcare professionals should refer to the Australian Product Information for VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle (AUST R: 199226) & VYVANSE lisdexamfetamine dimesilate 60 mg capsules bottle (AUST R: 284021) for indication and dosing information. This is available at: https://www.ebs.tga.gov.au/

VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) are identical in active ingredient, strength and contain the same excipient ingredients as the Australian registered products. They are registered and marketed in USA by Takeda Pharmaceuticals America, Inc.& therefore all labelling is in English.

It is important to note that the Australian registered VYVANSE lisdexamfetamine dimesilate capsules come in bottles of 30 capsules, whereas the S19A products VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (USA) come in bottles of 100 capsules.

Pharmacists should take extra care to ensure that the prescribed number of capsules are dispensed.

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Any adverse events which are experienced with VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (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 about VYVANSE lisdexamfetamine dimesylate capsules 50mg & 60mg (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 email sales@medsurge.com.au.

Kind regards,

Ramya.H.Gowda

Senior Regulatory Affairs Officer

Medsurge Healthcare