

25<sup>th</sup> August 2022

Dear Healthcare Professional,

**Availability of OLENA fluoxetine hydrochloride 20 mg dispersible tablet - under alternative supply arrangement of Section 19A of the Therapeutic Goods Act.**

Due to the shortage of the Australian registered ZACTIN fluoxetine hydrochloride 20 mg dispersible tablet (ARTG 90913), Reach Pharmaceuticals has arranged the supply of an alternative product called **OLENA fluoxetine hydrochloride 20 mg dispersible tablet**, registered and marketed in the United Kingdom.

**OLENA fluoxetine hydrochloride 20 mg dispersible tablet** is not registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **30 November 2022** for the following indications:

Treatment of:  
Major depression;  
Obsessive compulsive disorder (OCD).

The S19A approved UK product is identical in active ingredient and strength to the Australian registered product. A comparison table of differences between is given below:

	<b>ZACTIN fluoxetine hydrochloride 20 mg dispersible tablet (ARTG 90913)</b>	<b>S19A product - OLENA fluoxetine hydrochloride 20 mg dispersible tablet</b>
<b>Excipients</b>	Microcrystalline cellulose, colloidal anhydrous silica, maize starch, crospovidone, saccharin sodium, magnesium stearate, Nat. Peppermint Micron TIM-11812.	Mannitol (E421), croscarmellose sodium, magnesium stearate, saccharin sodium peppermint flavour*.  * Peppermint flavour contains sorbitol (E420) and sulfur dioxide (E220).
<b>Presentation</b>	Oval, normal convex, white tablet, debossed "FL / 20" on one side and "G" on the other.	Oblong, off white scored tablet with a length of 13mm and a diameter of 7.5mm.
<b>Storage</b>	Store below 30C.	Store below 30C. Store in the original package in order to protect from moisture.



**Please refer to the Australian Product Information for ZACTIN fluoxetine hydrochloride 20 mg dispersible tablet (ARTG 90913), when prescribing and dosing for the above indication.**

**Adverse Event Reporting**

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **OLENA fluoxetine hydrochloride 20 mg dispersible tablet** should be reported by healthcare professionals and patients to our Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Reach Pharmaceuticals Medical Information can be contacted by phone on 1800 505 306 or via email at [medical@reach-pharma.com](mailto:medical@reach-pharma.com)

**For sales related enquiries, please contact us on [sales@reach-pharma.com](mailto:sales@reach-pharma.com) or call 0422 429 648.**

We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

**Yours sincerely,**

Reach Pharmaceuticals Pty Ltd