

10th November 2023

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Dear Healthcare Professional

Shortage of ZACTIN TABS fluoxetine hydrochloride 20mg dispersible tablet blister pack (ARTG ID 90913) and alternative supply arrangement under section 19A of the *Therapeutic Goods Act 1989*

The Australian registered medicine ZACTIN TABS fluoxetine hydrochloride 20mg dispersible tablet blister pack (ARTG ID 90913) sponsored by Alphapharm Pty Ltd is currently unavailable or in short supply.

LINK has been able to arrange supply of an alternative product **Fluoxetine Capsules 10 mg (Medreich)** on a temporary basis. This product is 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 **31/5/2024** for the following indications:

- *Major depression;*
- *Obsessive Compulsive Disorder (OCD).*

Fluoxetine Capsules 10 mg (Medreich) is registered and marketed in **United Kingdom** therefore all labelling and packaging are in English.

It is important to note that **Fluoxetine Capsules 10 mg (Medreich)** contains ten milligrams (10mg) of fluoxetine per capsule and is intended to be used by suitable patients unable to access the Australian dispersible tablet product ZACTIN TABS fluoxetine hydrochloride 20mg dispersible tablet blister pack (AUST R 90913) and who cannot take 20mg capsule products.

Please refer to the Australian Product Information for ZACTIN TABS fluoxetine hydrochloride 20mg dispersible tablet blister pack (AUST R 90913) or ZACTIN fluoxetine hydrochloride 20mg capsule blister pack, both of which are available at www.ebs.tga.gov.au when prescribing and administering this substitute product. An overseas package leaflet is included with **Fluoxetine Capsules 10 mg (Medreich)** but please refer to the Australian Product Information for information about indications, dosing and administration, and warnings and precautions.

The table below outlines some important differences between the Australian registered **ZACTIN TABS fluoxetine hydrochloride 20mg dispersible tablet blister pack (ARTG ID 90913)** and the S19A product **Fluoxetine Capsules 10 mg (Medreich)**:

	ARTG product ZACTIN TABS fluoxetine hydrochloride 20mg dispersible tablet blister pack (ARTG ID 90913)	Section 19A approved medicine Fluoxetine Capsules 10 mg (Medreich)
Strength	20mg tablets	10mg capsules
Excipients		Pregelatinised starch Gelatin Sodium lauryl sulphate Iron oxide yellow (E 172) Patent blue V (E 131) Titanium dioxide (E 171)
Pack size	28 tablets	30 capsules

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 **Fluoxetine Capsules 10 mg (Medreich)** should be reported by healthcare professionals and patients to the LINK healthcare Pharmacovigilance at pv@linkhealthcare.co or 1800 181 060. Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>

Any product complaints regarding **Fluoxetine Capsules 10 mg (Medreich)** should be reported to LINK on 1800 161 181.

Please forward this information to relevant staff members in your organisation. For further information, please contact LINK on 1800 161 060 or email customerservice@linkhealthcare.com.au.

Yours faithfully



Kay Roweth
Unlicensed Medicine associate
Link Healthcare