16th January 2025

Dear Healthcare Professional,

Shortages of CONCERTA methylphenidate hydrochloride 18mg, 27mg, 36mg and 54mg modified release tablet bottles and alternate supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.

Australian registered CONCERTA methylphenidate hydrochloride products are currently or anticipated to be in shortage due to manufacturing issues.

Medsurge has been able to arrange for the supply of **CONCERTA methylphenidate hydrochloride 18 mg, 27 mg, 36 mg and 54 mg extended-release tablets (Switzerland)** as alternative products on a temporary basis.

These products are NOT registered in Australia, and supply is authorised under approvals granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until 30 June 2025. for the following indication:

• *CONCERTA is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).*Treatment should be commenced by a specialist.

The section 19A approved products **CONCERTA methylphenidate hydrochloride 18 mg, 27 mg, 36 mg and 54 mg extended-release tablets (Switzerland)** are identical in active ingredient and strength to the Australian registered products. The labelling is in German, however identifiable for Healthcare Professionals and patients. Differences between the ARTG and section 19A product are outlined below.

	ARTG product:	**S19A Product:**
	• CONCERTA methylphenidate hydrochloride 18mg modified release tablet bottle (AUST R: 93862) • CONCERTA methylphenidate hydrochloride 27mg modified release tablet bottle (AUST R: 124502) • CONCERTA methylphenidate hydrochloride 36mg modified release tablet bottle (AUST R: 93863) • CONCERTA methylphenidate hydrochloride 54mg modified release tablet bottle (AUST R: 93864)	• Concerta methylphenidate hydrochloride 18 mg extended-release tablets (Switzerland) • Concerta methylphenidate hydrochloride 27 mg extended-release tablets (Switzerland) • Concerta methylphenidate hydrochloride 36 mg extended-release tablets (Switzerland) • Concerta methylphenidate hydrochloride 54 mg extended-release tablets (Switzerland)

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Inactive ingredients	• butylated hydroxytoluene • carnauba wax • cellulose acetate • hypromellose • lactose monohydrate • phosphoric acid • poloxamer • polyethylene oxide • povidone • sodium chloride • stearic acid • succinic acid • iron oxide black • iron oxide yellow • iron oxide red (27 mg and 54 mg tabs only) • OPACODE WB monograming ink NS-78-17715 Black (PI 4424) • OPADRY complete film coating system YS-1-19025-A Clear (PI 4421) • OPADRY II complete film coating system YS-30-12788-A YELLOW (PI 10244) (18 mg tabs only) • OPADRY II complete film coating system Y-30-17528 GRAY (PI 12131) (27 mg tabs only) • OPADRY II Y-30-18037 WHITE (PI 3667) (36 mg tabs only) • OPADRY II complete film coating system Y-30-15567-A RED (PI 10245) (54 mg tabs only)	• butylated hydroxytoluene (E 321), • cellulose acetate, • hypromellose, •concentrated phosphoric acid, • poloxamer 188, • macrogol 200,000 and 7,000,000, • povidone K 29-32, •sodium chloride, •stearic acid, •succinic acid, •iron oxide black and yellow (E 172). •27 mg and 54 mg extended-release tablets: iron oxide red (E 172). •*Film coating:* hypromellose, lactose monohydrate, titanium dioxide (E 171), triacetin, carnauba wax, macrogol 400. •18 mg extended-release tablet: additional iron oxide yellow (E 172), stearic acid. •27 mg extended-release tablet: additional iron oxide black (E 172). •54 mg prolonged-release tablet: additional iron oxide red and yellow (E 172). •*Printing ink:* Iron oxide black (E 172), hypromellose, propylene glycol. *Total Sodium Content*: 18 mg prolonged-release tablet: 7.08 mg; 27 mg extended-release tablet: 7.08 mg; 36 mg prolonged-release tablet: 14.16 mg; 54 mg prolonged-release tablet: 14.16 mg. *Lactose content:* 18 mg prolonged-release tablet: 6.5 mg; 27 mg extended-release tablet: 4.9 mg, 36 mg extended-release tablet: 16.7 mg; 54 mg extended-release tablet: 7.6 mg.
Pack size	Pack of 28, 30, 56, 60 or 100 tablets	Pack of 30 and 60 tablets (30x2)
Storage	Store below 25°C. Keep container tightly closed.	Store at room temperature (15-25 °C). Keep the container tightly closed. Keep out of reach of children.

Health Professionals should advise patients that CONCERTA methylphenidate hydrochloride 18 mg, 27 mg, 36 mg and 54 mg extended-release tablets (Switzerland), contain lactose, and sodium and ensure it is appropriate for the patient.

For prescribing and administration, please refer to the Australian Product Information for **CONCERTA methylphenidate hydrochloride 18mg, 27mg, 36mg and 54mg modified release tablet bottle** available at www.ebs.tga.gov.au

Adverse Event Reporting

Any adverse events which are experienced with section 19A approved products **Concerta methylphenidate hydrochloride 18 mg, 27 mg, 36 mg and 54 mg extended-release tablets (Switzerland)** should be reported by

healthcare professionals to Medsurge on 1300 788 261 or email customerservice@medsurgehc.com. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Any product complaints with **Concerta methylphenidate hydrochloride 18 mg, 27 mg, 36 mg and 54 mg extended-release tablets (Switzerland)** should be reported to Medsurge on 1300 788 261 or email customerservice@medsurgehc.com.

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

For further information, please contact Medsurge Healthcare on 1300 788 261 or at email customerservice@medsurgehc.com.

Kind regards,

Ramya.H.Gowda

Senior Regulatory Affairs Officer

Medsurge Healthcare