

## Switch to cheaper bio-equivalent brand of Concerta XL: Advice to Healthcare Professionals

### Recommended brands: Delmosart XL, Xaggitin XL

#### Summary

The following brief provides recommendations for CAMHS/ Paediatricians/ CCGs/JPC. Where clinically appropriate if a young person requires a release profile matching that of Concerta XL, to consider Delmosart XL or Xaggitin XL for new initiations, and a switch for existing patients.

The bulletin is recommending Delmosart XL and Xaggitin XL based on cost comparison and the price guarantee provided by the Manufacturers. These two bio-equivalent brands also come in a range of strengths similar to Concerta XL.

Initiation for new patients would require titration in keeping with other ADHD medication. Switch for existing patients from Concerta XL would be to an equivalent dose. No titration and/ or cross over of treatment are required. Young persons can also be switched from immediate release to Delmosart XL/Xaggitin XL.

Generic prescribing of Methylphenidate modified release is not recommended due to cost implications, variability in brand supply, difficulty in monitoring treatment efficacy and potential for medication incidents.

This bulletin is a recommendation only, and as always the CAMHS/Paediatrician should prescribe brand and formulation based on the needs of the young person. Any brand switch/ initiation must be done in agreement with the parent/carer and where appropriate the young person. Brand specific medication information should be provided as appropriate.

#### Background

Attention Deficit Hyperactivity Disorder (ADHD) is characterised by a combination of behavioural, emotional and cognitive deficits. Core symptoms include impulsivity, hyperactivity, poor attention and concentrations.

There are now a range of stimulants and non-stimulants available within the NHS for treatment of ADHD in children and adolescents. The first line drug, remains Methylphenidate which is available as an immediate release (IR) and modified release formulation.

The modified release preparations have both an immediate release and sustained release component. The CAMHS/ Paediatrician have the option of three different formulations, based on the release profile and what suits the clinical needs of the patient.

The branded products with the three release profiles are as follows:

Concerta XL (immediate release- 22%; sustained release-78%)

Equasym XL (immediate release- 30%; sustained release- 78%)

Medikinet XL (immediate release- 50%; sustained release- 50%)

The following information and switch recommendation is for Concerta XL only. If a young person requires a different release profile, then the advice is to prescribe one of the above branded products.

## Brands bio-equivalent to Concerta XL

There are currently four brands which are bio-equivalent to Concerta XL. These are Matoride XL, Xenidate XL, Xaggitin XL and Delmosart XL.

This recommendation will focus on **Xaggitin XL** and **Delmosart XL** for the following reasons:

Bio-equivalence and efficacy

Strength availability and appearance same/ similar to Concerta XL

Cost in comparison to Matoride XL and Xenidate XL

### Product Comparison

		Concerta XL	Delmosart XL	Xaggitin XL
Formulations		18mg, 27mg, 36mg, 54mg tablets	18mg, 27mg, 36mg, 54mg tablets	18mg, 27mg, 36mg, 54mg tablets
License			6 years and over	
Appearance	18mg	Capsule-shaped yellow tablet with “alza 18” printed on one side in black ink	Capsule-shaped, biconvex, <u>yellow tablet</u> , with “2392” printed on one side in black ink	Capsule-shaped, biconvex, <u>yellow tablet</u> , with “2392” printed on one side in black ink.
	27mg	Capsule-shaped grey tablet with “alza 27” printed on one side in black ink	Capsule-shaped, biconvex, <u>grey tablet</u> , with “2393” printed on one side in black ink	Capsule-shaped, biconvex, <u>grey tablet</u> , with “2393” printed on one side in black ink.
	36mg	Capsule-shaped white tablet with “alza 36” printed on one side in black ink	Capsule-shaped, biconvex, <u>white tablet</u> , with “2394” printed on one side in black ink	Capsule-shaped, biconvex, <u>white tablet</u> , with “2394” printed on one side in black ink
	54mg	Capsule-shaped brownish-red tablet with “alza 54” printed on one side in black ink	Capsule-shaped, biconvex, <u>red-brown tablet</u> , with “2395” printed on one side in black ink	Capsule-shaped, biconvex, <u>red-brown tablet</u> , with “2395” printed on one side in black ink
Half life		3.5 ± 0.4 (h)	3.5 ± 0.4 (h)	
Release profile		Initial maximum drug concentration at about 1 to 2 hours Peak plasma concentrations are achieved at about 6 to 8 hours	Initial maximum methylphenidate concentration at about 1 to 2 hours Peak plasma concentrations are achieved at about 6 to 8 hours	Initial maximum methylphenidate concentration at about 1 to 2 hours Peak plasma concentrations are achieved at about 6 to 8 hours
Duration of action		Upto 12 hours	Upto 12 hours	Upto 12 hours
		Can be taken with or without food	Can be taken without food	Can be taken without food
Frequency		Once daily	Once daily	Once daily
Immediate release equivalent		XMG three times a day	XMG three times a day	XMG three times a day
Switch from Concerta XL			Equivalent dose switch. No titration required.	Equivalent dose switch. No titration required.

## Cost comparison

Cost per unit (£)/ pack size	Concerta XL	Delmosart XL	Xaggitin XL
<b>18mg</b>	31.19 (30)	15.59 (30)	15.58 (30)
<b>27mg</b>	36.81 (30)	18.41 (30)	18.40 (30)
<b>36mg</b>	42.45 (30)	21.23 (30)	21.22 (30)
<b>54mg</b>	73.62 (30)	36.81 (30)	36.80 (30)

### Price Guarantee

Ethypharm UK (Xaggitin) have confirmed they will not increase the price of Xaggitin, subject to there being no material change either to the Category C of the Drug tariff (England and Wales) or the current PPRS scheme.

Activis UK (Delmosart) have confirmed they will not increase the NHS list price for Delmosart in the next 24 months (from 2017).

### Generic Prescribing

Generic prescribing as Methylphenidate modified release tablets is **not recommended** for the following reasons:

Since Methylphenidate is a Category C drug any generic prescriptions will be charged at the highest cost price which in this case would be Concerta XL.

Prescriptions with generic prescribing will result in the patient potentially receiving different brands and this variability makes it difficult for the clinician to ascertain therapeutic benefit and/ or judge efficacy.

Methylphenidate MR has three different release profiles, generic prescribing has the potential to lead to medication incidents with formulation.

Patient choice is also very important and brand prescribing provides choice, stability and monitoring of efficacy vs. side effects.

### Recommendation

The following is a recommendation only. As always the choice of brand and formulation is based on the patient's needs and the clinical judgement of the prescriber (CAMHS/Paediatrician/GP).

It is the responsibility of the CAMHS consultant/ Paediatrician to communicate to the GP the brand to prescribe. This applies both for initiation and where a brand switch has been agreed with the parent/carer and young person.

There is a shared care agreement in place for ADHD which stipulates the duties of each of the professional group. Please refer to this for guidance and/ or further information.

The shared care does not specify a particular brand of Methylphenidate. This is because the length of time shared care agreements remain in place creates the potential of brand information becoming out-dated and/ or no longer relevant. However, there is a statement within the shared care stipulating CAMHS/ Paediatrician/CCG/GPs to prescribe the recommended bio-equivalent brand to Concerta XL as agreed in this recommendation.

### Parent/carer and Young person

It is important for either a new initiation and/ or switch from Concerta XL to one of the recommended brands, that parents/ carers and where appropriate young persons are part of the discussion.

Rationale for the switch and medication information must be provided to parent/carer and young person to make an informed decision. Particularly in the case of a brand switch, there must be an agreement between the clinician, parent/carer and where appropriate the young person.

Written medication information on the brand should be provided.

#### **New initiation**

For titration and dosing, please follow as per summary product recommendations and current edition of BNF.

#### **Switching from Concerta XL**

The young person can be switched from Concerta XL to an equivalent dose of Xaggitin or Delmosart e.g. Concerta XL 18mg in the morning = Delmosart XL 18mg in the morning.

Bioequivalent brands do not require not a cross over from one medication to the other. A titration to the new brand is also not required.

#### **Switching to Xaggitin XL/ Delmosart XL from IR Methylphenidate**

The recommended switch from immediate release Methylphenidate is based on Xmg three times a day.

Both brands provide guidance on the equivalent dose of sustained release once daily dosing based on the current mg taken three times a day.

Please refer to the summary of product characteristics for this information.

#### **Further information:**

Concerta XL: <https://www.medicines.org.uk/emc/medicine/30451>

Xaggitin XL: <https://www.medicines.org.uk/emc/medicine/33527>

Delmosart: <https://www.medicines.org.uk/emc/medicine/32790>