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Circular 022 / 16

Re: Important Information - Patients on Lithium Carbonate

17 May 2016

Dear Pharmacist,

Please find enclosed guidance for transitioning patients from Camcolit® to the alternative Lithium Carbonate product in the Irish marketplace, Priadel®. This is required as Camcolit® will be shortly unavailable through the GMS and Community Drug Schemes. This guidance has been developed by the Medicines Management Programme in collaboration with the Mental Health Directorate. The Guidance Note enclosed will also be distributed through the Hospital network and clinical community in that setting.

The discontinuation under Schemes of Camcolit® became necessary as the HSE did not accede to a very substantial price increase request occasioned by the divestment of the Camcolit® range of products from Norgine to Essential Pharma in 2015. It should be noted that most European countries outside of the UK do not market the Camcolit® products.

The Camcolit® range of products will not receive reimbursement support from the HSE through the Exempt Medicinal Products Protocol and patients should be transferred to the alternative product in the coming weeks.

Yours sincerely,

Anne Marie Hoey

Anne Marie Hoey
Primary Care Reimbursement & Eligibility

Lithium Carbonate tablets

IMPORTANT INFORMATION FOR PRESCRIBERS AND PHARMACISTS

CHANGING PATIENTS FROM CAMCOLIT® TO PRIADEL® TABLETS

Lithium tablets contain lithium carbonate and two brands are currently available: Priadel® and Camcolit®.[1]

The bioavailability will vary from product to product (particularly with regard to retard or slow release preparations) however there is no clinically significant difference in the pharmacokinetics of the two most widely prescribed brands of lithium: Priadel® and Camcolit®.[2] Table 1 lists the tablet preparations and doses currently available.

Table 1: Lithium Carbonate products and doses available[3,4,5,6]

Lithium Preparations	Lithium salt	Doses available
Camcolit®	Lithium carbonate	250mg 400mg
Priadel®	Lithium carbonate	200mg 400mg

Lithium has a narrow therapeutic range and therefore monitoring of plasma lithium levels is required. It is also recommended that a change of product (in this case from Camcolit® to Priadel® tablets) should be regarded as initiation of new treatment and that close monitoring of plasma concentrations is necessary.[3,4]

To facilitate the safe transfer of patients from Camcolit® tablets to Priadel® tablets the MMP recommends the following:

1. Plasma lithium level is taken first.
2. Priadel tablets are prolonged release and are recommended to be given once daily at night.
3. Priadel® is started (discontinue Camcolit®) at a DAILY DOSE as close as possible to the dose of the previous prescription.
4. In most cases, a direct switch from Camcolit® to the same dose of Priadel® is feasible eg. Camcolit® 1000mg nocte to Priadel® 1000mg nocte. In some cases, due to different strengths available, a direct switch is not feasible eg. Camcolit® 650mg nocte may be changed to Priadel® 600mg or 700mg nocte. The dose selected should be based on the plasma lithium level and the target therapeutic range.
5. The 200mg Priadel tablets have a break line and may be halved.[7] While halving of the 200mg tablet is outside of Irish licensing, it is stated in the UK SmPC that tablets can be divided accurately to provide a dosage requirement as small as 100mg.[7]
6. For patients taking Camcolit® tablets twice daily it is recommended to switch to Priadel once daily at night e.g. Camcolit® 500mg twice daily may be changed to Priadel® 1000mg at night. On the day of the switch omit the morning Camcolit® dose and take the full Priadel® dose that night.
7. Plasma lithium levels should be measured again five to seven days after Priadel® initiation.
8. Lithium levels are recommended to be taken 12 hours post- dose (11-13 hours post- dose if necessary).[2]
9. Plasma lithium levels should be monitored weekly until stabilisation is achieved.[3,4]
10. Plasma lithium levels of 0.4mmol/L may be effective in unipolar depression; 0.6-1.0mmol/L in bipolar disorder; slightly higher levels in difficult to treat mania.[2] When lithium levels are being monitored in relation to a change of brand, where doubt exists with respect to the appropriate lithium level for an individual, the patients psychiatrist should be consulted for guidance.
11. Plasma lithium levels should then be measured every 3 months (for the next year), as per standard recommendations for lithium monitoring, and every 3-6 months thereafter, as clinically appropriate. [1,2,8,9]

Signs of lithium toxicity (levels >1.5mmol/L)

- Gastrointestinal disorders – increasing anorexia, nausea, vomiting, diarrhoea
- Nervous system disorders: Encephalopathy, cerebellar syndrome with symptoms such as muscle weakness, lack of coordination, drowsiness or lethargy, giddiness, ataxia, nystagmus, coarse tremor, tinnitus, blurred vision, dysarthria, twitching, myoclonus, extrapyramidal disorders.
- ECG changes – flat or inverted T waves, QT prolongation
- AV block, dehydration and electrolyte disturbances [1,2,3,4]

Standard information on the full monitoring requirements for patients on lithium therapy (including the monitoring of plasma lithium levels, renal function, cardiac function, thyroid function, body weight and interacting drugs etc.) still applies to all patients on lithium therapy and information on this is available from a number of resources:

- British National Formulary
- Summary of Product Characteristics for Priadel®
- The Maudsley Prescribing Guidelines
- NICE Clinical Guideline No. 185. Bipolar disorder: assessment and management (available on: http://www.nice.org.uk/guidance/cg185/resources/bipolar-disorder-assessment-and-management-35109814379461).
- IMSN Best Practice Guidelines for Prescribing and Monitoring of Lithium Therapy (available on: http://www.imsn.ie/images/guidelines/imsn-lithium-guidelines-may-2012.pdf)
- National Lithium patient information packs are available to order from KPW Print Tel: 090 9642297

Note: Liquid formulations of lithium contain **lithium citrate**; tablet formulations contain **lithium carbonate**. Priadel® liquid contains 520mg lithium citrate in 5mL (equivalent to Lithium Carbonate 204mg), so 5ml of Priadel® liquid is approximately equivalent to 200mg of lithium carbonate.[9,10]
Priadel® liquid should be prescribed in divided doses twice daily; in the morning and at night.[9]
Close monitoring of patients' plasma lithium levels is also required if changing from tablet formulations to liquid.

These recommendations have been reviewed by clinical pharmacists working in Mental Health in the HSE, St John of Gods Hospital and St Patricks Hospital.

References:

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5. Camcolit 250mg Film Coated tablets, May 2015. Accessed at http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1994-001-001_22102015170055.pdf on 20/04/2016 on 20/04/2016.
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8. National Institute for Health and Care Excellence. NICE Guidelines. Clinical Guideline No. 185. Bipolar disorder: assessment and management, September 2014. Accessed at: www.nice.org.uk on 07/03/2016.
9. IMSN Best Practice Guidelines for Prescribing and Monitoring of Lithium Therapy (available at http://www.imsn.ie/images/guidelines/imsn-lithium-guidelines-may-2012.pdf)
10. EMC. Summary of Product characteristics for Priadel® Liquid. Available at www.medicines.org.uk