Business Services Organisation

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# Medicine Supply Notification: Oxybutynin 5mg modified-release tablets

Tier 2 – medium impact*
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Medicines Supply Tool – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

## Summary


- Oxybutynin 5mg modified-release tablets are out of stock until early April 2024.
- Oxybutynin immediate release formulations (tablets and liquid) remain available and can support increased demand, as can alternative anticholinergic agents.


## Actions Required

Where patients established on oxybutynin 5mg modified-release tablets have insufficient supplies to last until the re-supply date, prescribers should:

- review patients to determine if this is still the most suitable therapy. Where appropriate, consider switching to (or re-trialling) immediate release oxybutynin tablets or oral solution, at the same total daily dose, but administered in divided doses - dose re-titration may be needed, based on symptoms and tolerability (see supporting information); or
- if above options are not suitable, consider use of another anticholinergic agent (see supporting information).

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Supporting Information

Clinical information

Oxybutynin is licensed:

- in adults for the symptomatic treatment of urge incontinence and/or increased urinary frequency associated with urgency as may occur in adult patients with unstable bladder.
- in children over 5 years for urinary incontinence, urgency and frequency in unstable bladder conditions due to idiopathic overactive bladder or neurogenic bladder disorders (detrusor overactivity), and nocturnal enuresis associated with detrusor overactivity, in conjunction with nondrug therapy, when other treatment has failed.

Dose of immediate release tablets

- In adults, the usual dose is 5 mg two or three times a day, which may be increased to a maximum of 5 mg four times a day (maximum dose 20 mg).

- In the elderly, elimination half-life is increased, therefore, a dose of 2.5 mg twice a day, particularly if the patient is frail, is likely to be adequate, which may be increased to 5 mg twice a day.

- In children, usual dose is 2.5 mg twice a day which may be increased to 5 mg two or three times a day. For nocturnal enuresis, the last dose should be given before bedtime.

The SmPC for the modified-release tablets does not include a dose conversion when switching from an immediate release to the modified-release formulation. It advises clinical judgement should be exercised in selecting the appropriate dose of the modified-release formulation, which should be adjusted to the minimum dose that achieves an optimal balance of efficacy and tolerability, taking into account the current immediate-release dose.

The BNF and BNFc suggest that patients taking immediate-release oxybutynin may be transferred to the nearest equivalent daily dose of a modified-release formulation. Pragmatic advice therefore is to switch patients currently on modified-release oxybutynin to the equivalent daily dose of immediate-release oxybutynin split into two or three divided doses. Oxybutynin has a very short half-life (2-3 hours) so some patients may require the dose to be re-titrated.

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Anticholinergic side effects

Dry mouth is the most common and troublesome adverse effect of anticholinergic medicines and is the main reason for discontinuing oxybutynin. As many of these adverse effects are dose-related, it is recommended that doses should be titrated according to response and side effects, with lower doses generally used in the elderly.

For patients experiencing side-effects or with inadequate response at maximum dose, changing to a different anticholinergic agent may be beneficial as side-effect profiles differ. For example, solifenacin and tolterodine are considered to cause dry mouth to a lesser extent than oxybutynin. Extended-release formulations of anticholinergic medicines are also expected to reduce the risk of dry mouth. The SmPC for modified-release oxybutynin notes in clinical studies, dry mouth has been less frequently reported than with immediate release formulations.

Please refer to the links below

- Oxybutynin 5mg modified-release 5mg prolonged release tablets Microsoft Word - 6834530007747124362_spc-doc.doc (windows.net)
- SmPC: Oxybutynin products Search Results - (emc) (medicines.org.uk)
- SmPC: Tolterodine preparations Search Results - (emc) (medicines.org.uk)
- SmPC: Solifenacin preparations Search Results - (emc) (medicines.org.uk)
- BNF: Urinary incontinence in women Urinary incontinence and pelvic organ prolapse in women | Treatment summaries | BNF | NICE
- BNFc: Urinary frequency, enuresis and incontinence Urinary incontinence and pelvic organ prolapse in women | Treatment summaries | BNF | NICE
- BNFc: Nocturnal enuresis in children Nocturnal enuresis in children | Treatment summaries | BNFC | NICE
- CKS: LUTS in men - overactive bladder Scenario: Overactive bladder | Management | LUTS in men | CKS | NICE