BNSSG Paediatric Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Mirabegron
Amber ***three months***	
Indication	Overactive bladder syndrome

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	5-15 years: initially 25mg once a day, increased to 50mg if necessary (unlicensed in children)
Route and formulation	Oral Prolonged-release tablets 25mg and 50mg
Duration of treatment	Patient dependent. Duration based on specialist doctor's discretion

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Blood pressure and heart rate

(ECG monitoring is not required as a baseline test)

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	Frequency	Who by	Action/management
Blood pressure	Each hospital review	Secondary care: urology nurse, hospital team in clinic	Refer to urology team if concerned about high BP
Heart rate	Each hospital review	Secondary care: urology nurse, hospital team in clinic	Refer to urology team if concerned about high HR

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

<table>
<tr><td>Side effects and management</td><td>
<table>
<tr><th>Side effect</th><th>Frequency/severity</th><th>Action/management</th></tr>
<tr><td>Urinary tract infections</td><td rowspan="3">Common (≥1/100 to <1/10)</td><td>GP to treat UTI if required and refer to specialist urology team if recurrent</td></tr>
<tr><td>Tachycardia
Arrhythmias</td><td>Refer to specialist urology team urgently</td></tr>
<tr><td>Headache
Dizziness
Nausea, constipation, diarrhoea</td><td>Refer to specialist urology team if prolonged or severe symptoms</td></tr>
</table>
</td></tr>
<tr><td>Referral back to specialist</td><td>Refer to specialist team if there are any concerns with possible side effects.
Please complete a Yellow Card to report side effects.</td></tr>
</table>

Section 5: Other Issues
(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues	Contraindications: Patients with severe uncontrolled hypertension Not recommended for patients with severe renal impairment Severe hepatic impairment Cautions: Reduce dose in patients with mild or moderate renal impairment Congenital or acquired QT prolongation or patients taking concomitant QT prolonging drugs Bladder outlet obstruction Drug interactions: • CYP3A enzyme inducers, e.g. rifampicin, decrease the plasma concentration of mirabegron. No dose adjustment is required • CYP3A enzyme inhibitors, e.g. clarithromycin, increase exposure of mirabegron. No dose adjustment is required • Increased risk of QT prolongation with concomitant use of medicines that also cause QT prolongation, e.g. ondansetron. Avoid concomitant use of these medicines
Reminder to ask patient about specific problems	Ask about effectiveness of mirabegron Ask about any possible side effects

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Swallow whole, do not chew or crush the tablet

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

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Section 10: Document Details

Date prepared	20/06/2022
Prepared by	Fiona Sinclair (Paediatric Pharmacist) Olivia Stillwagon (Surgical Paediatric Pharmacist)
Date approved by JFG	December 2022
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Document Identification: Version	V1

Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Click here to enter details

Section 12: References

Please list references

1. SPC. *Betmiga 25mg & 50mg prolonged-release tablets.* Available from: https://www.medicines.org.uk/emc/medicine/27429# [Accessed 05/04/212].
2. Evelina Paediatric Formulary. *Mirabegron.* Available from mobile ap. [Accessed 05/04/22].
3. BNFC. *Mirabegron.* [Accessed 05/04/22].