12th September 2019

Dear Colleagues,

Please be aware that there is an important drug supply issue affecting:

**Mianserin 10mg and 30mg tablets**

* Mylan, the sole supplier of mianserin tablets, have informed the Department of Health and Social Care (DHSC) that due to manufacturing delays, both strengths are out of stock until the end of 2019.

**Action required by recipients:**

* For patients who do not have sufficient supplies of mianserin tablets for the duration of the expected out of stock period, **clinicians should consider prescribing an unlicensed preparation** of mianserin tablets as soon as possible in order to avoid abrupt withdrawal.
	+ DHSC have contacted specialist importer companies who have advised that unlicensed imports can be sourced from abroad.
	+ Importers who have currently confirmed they can source these lines, include:

|  |  |
| --- | --- |
| Mianserin 10mg tablets | Alium Medical |
| Target Healthcare LTD |
| Mawdsley’s |
| Mianserin 30mg tablets | Alium Medical |
| Target Healthcare Ltd |
| Mawdsley’s |
| Durbin PLC |

* + Clinicians will need to work with local pharmacies to understand more about the specific unlicensed products that can be sourced and associated lead times.
	+ Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:

<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf>

<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/specials-professional-guidance.pdf>

* + In order for pharmacies to dispense an unlicensed drug, FP10 prescriptions must indicate that a special is required/prescribed by the GP. This could include the GP annotating the prescription with the following wording: “special order”.
* To minimise the disruption this may cause locally in terms of patients seeking GP appointments, GP practices may want to consider using local IT systems to identify patients who may be impacted by this shortage and to manage these patients by prescribing unlicensed supplies or seeking specialist secondary care advice in good time, where appropriate.
* For patients **in whom unlicensed imports are not considered appropriate**, clinical advice provided by national specialists within NHE/I advises the following management plan:

Patients who have been prescribed mianserin for < 6 months

1. GP to start mirtazapine at a low dose depending on clinical judgement and the Summary of Product Characteristics (SPC)
2. Consider psychological therapies

Patients who have been prescribed mianserin for > 6 months

1. GP to start mirtazapine at a low dose depending on clinical judgement and the SPC
2. Seek specialist secondary care advice on management options

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk

We hope this information is helpful and thank you for your assistance with this issue.

Yours sincerely,

DHSC Medicines Supply team