12th September 2019

Dear Colleagues,

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

**Tiagabine\* (Gabitril) 5mg, 10mg and 15mg tablets**

* Teva, the sole supplier of tiagabine tablets, have informed the Department of Health and Social Care (DHSC) that due to manufacturing delays, all strengths will be out of stock until the end of October 2019.
* A limited number of 10mg tablets remain available through the wholesaler, Alliance Healthcare. If pharmacies are unable to obtain from their usual Alliance depot, inform Teva customer services who will liaise with the wholesaler to redistribute stock to where it is required (an account with Alliance Healthcare will be required).

\*Tiagabine in classed as a category 3 anti-epileptic drug (AED) by the MHRA. T**his means that individuals can be switched between different versions of their AEDs** and that these AEDs can be prescribed generically**.**

**Action required by recipients:**

* For patients who do not have sufficient supplies of tiagabine tablets for the duration of the expected out of stock period, **clinicians should consider prescribing an unlicensed preparation** of tiagabine tablets as soon as possible.
  + 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:

|  |  |
| --- | --- |
| Tiagabine 5mg/10mg/15mg tablets | Durbin PLC |
| Target Healthcare LTD |
| Mawdsley’s |

* + 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 referring back to a specialist team in good time, where appropriate.
* For patients **in whom unlicensed supplies are not considered appropriate** a referral to secondary care specialists will be required for consideration of alternative options.

If you have any queries, please contact [DHSCmedicinesupplyteam@dhsc.gov.uk](mailto: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