

Ref PH600

To all Community Pharmacies in the Wessex area and copied to Partner organisations and other interested parties for information

Please see below information regarding supply issues with Labetalol tablets (all strengths) AND Levomepromazine 25mg/ml.

Please cascade this information within your teams and organisations (share as appropriate). This information is being shared with all community pharmacy contractors and general practice colleagues via Heads of primary care and hospital pharmacy colleagues via regional pharmacists.

1) URGENT - Supply issues with Labetalol tablets – all strengths

DHSC has been made aware of a supply issue with the following products and as a result, supplies will be very limited from April until early-mid May.

- Labetalol 50mg tablets;
- Labetalol 100mg tablets;
- Labetalol 200mg tablets;
- Labetalol 400mg tablets.

There are two suppliers of labetalol tablets in the UK, Mylan and Recipharm:

- Mylan have had a delay in resupply due to an internal delay in serialisation of FMD packs, further stock is expected in early-mid May.
- Recipharm have experienced an issue with the active pharmaceutical ingredient and currently unable to provide a resupply date.

Prescribers should be aware that no new patients should be commenced on labetalol during this time as there are currently very limited stocks available.

Labetalol is indicated for the management of hypertension, particularly in pregnancy. Patients who do not have sufficient supplies to last until early May and who are unable to obtain supplies of labetalol will need to be switched to an appropriate alternative treatment during this time. The clinical management plan for pregnant patients will be different to patients who are not pregnant.

Please see a memo developed by UK Medicines Information with input from national experts at NHSE and NHSI, which advises on management options for patients affected by this supply issue, including the use of alternative anti-hypertensives during pregnancy. This is available on the SPS website at the following link: <https://www.sps.nhs.uk/articles/shortage-of-labetalol-tablets/>

Suppliers of the clinical alternatives are aware of the issue. Manufacturers of both nifedipine modified release and methyldopa are confident they are able to support any additional demand on their products during this time.

Different versions of modified-release preparations may not have the same clinical effect. Prescribers should liaise with their community pharmacy to determine which brands of nifedipine modified release tablets are currently available in your area.

Suppliers of alternative beta blockers have been contacted to determine if they can meet any additional demand and currently, the manufacturers of carvedilol and metoprolol have indicated they would be unable to meet demand if patients were switched to this product. Manufacturers of bisoprolol, atenolol and propranolol have indicated they have capacity to support any additional demand on their products.

Some specialist importers have identified unlicensed stock they can bring into the UK from abroad. Lead times for these products vary between 7 and 21 days. Under the medicines legislation, doctors can prescribe unlicensed products for their patients if they think it appropriate, but do so entirely on their own responsibility.

2) URGENT Levomepromazine 25mg/ml injection supply issue – information for Primary Care

Overview of Supply

Sanofi informed NHS England and DHSC on 5th April 2019 that they are going out of stock this week of levomepromazine 25mg/ml injection and new stock is expected to be available from the end of April. The supply issue is due to a quality deviation experienced at their Italian factory and is not linked to EU exit.

The only other UK supplier, Wockhardt, have informed us that due to the unexpected increase in demand, they will also go out of stock of levomepromazine injection and their next delivery has been delayed with further stock expected at the end of April.

- Wockhardt have confirmed the remaining levomepromazine 25mg/mL injection stock which is held at Alliance will be ring-fenced for primary care use only. Stock at Alliance is limited and will not last until the end of April.
- Existing stocks are likely to be exhausted by end of this week and no new supplies are expected until end of April.
- GPs, palliative care networks and community pharmacies should consider the following advice and work together during this period to ensure patients can be managed appropriately.

Alternative agents

UK Medicines Information with support of national clinical specialists have developed the following clinical information to help support the management of patients who may be affected by this issue. Please follow the link to view this guidance: <https://www.sps.nhs.uk/articles/shortage-of-levomepromazine-hydrochloride-25mg-ml-solution-for-injection/>

All the suppliers of the following medicines have been made aware of this supply issue and have confirmed they can support an increase in demand should this be required.

- Haloperidol 5mg/1ml solution for injection ampoules (DrugsRUs)
- Midazolam 10mg/2ml solution for injection ampoules (Hameln, Accord, Roche)
- Cyclizine 50mg/ml solution for injection ampoules (Advanz)
- Metoclopramide 10mg/2ml solution for injection ampoules (Hameln, Ennogen)

Management Plan - GPs, Palliative Care Networks and Community Pharmacies to review and action immediately

1. During the period of shortage, new patients should only be started on levomepromazine if other treatment options have been exhausted. This is to try to avoid disrupting existing treatment regimens where possible whilst acknowledging that for some new patients levomepromazine may be the only option available.
2. Community pharmacies who require stock for existing patients should order Wockhardt stock from Alliance.
3. Community pharmacies having difficulty obtaining stock should contact their local secondary care trusts as they have been asked to support primary care and hospices where possible, to understand if they have stock that can be made available to allow the continuation of treatment in existing patients.
4. Some specialist importers have identified stock they can bring into the UK. Lead times vary between 7-21 days. If community pharmacies are considering ordering unlicensed imports, the community pharmacist will need to inform the prescribing doctor the product being supplied to the patients is an unlicensed product. Please consider placing orders now for 1-2 weeks of stock based on forecasted demand. We are currently aware that Clinigen, Waymade, Alium and Mawdsleys have sourced unlicensed supplies from abroad.
5. Community pharmacies unable to obtain levomepromazine injection should liaise with the prescriber to discuss using an alternative product as outlined in the memo – link above.

Kind regards

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