

Supply Disruption Alert

SDA/2020/010

Issued: 29 May 2020

Zyban® (bupropion hydrochloride) 150mg prolonged release tablets – Supply Disruption

Summary

- Zyban® (bupropion hydrochloride) 150mg prolonged release tablets will be out of stock from week commencing 15th June 2020 until the end of November 2020.
- Unlicensed supplies of bupropion 150mg prolonged release tablets have been sourced.
- Champix® (varenicline tartrate) tablets, which are licensed for the treatment of nicotine dependence, are available.
- Various nicotine replacement therapies (NRT) are also available.

Action

All healthcare professionals in primary, secondary or specialist healthcare services including local stop smoking services, should work with clinicians including pharmacists to ensure the following actions are undertaken where relevant:

- defer initiating new patients on Zyban® 150mg prolonged release tablets until the supply disruption is resolved;
- for patients taking Zyban® as a smoking cessation aid, clinicians should consider alternative pharmacotherapy options (see further advice below);
- be aware that unlicensed bupropion 150mg prolonged release tablets cannot be issued against a Patient Group Direction (PGD); and
- GPs to identify any patients currently prescribed Zyban® 150mg prolonged release tablets for off-label use (e.g. treatment resistant depression) and:
 - make early contact with the patient or patient's carer to allow time to plan for any withdrawal/switch strategies;
 - consider prescribing unlicensed bupropion 150mg prolonged release tablets if appropriate;
 - refer patients to their secondary care specialist for individual review if unlicensed bupropion tablets are not considered appropriate.

Deadlines for actions

Actions initiated: on receipt of this alert

Actions completed: 30/11/2020

Product details

Zyban® (bupropion hydrochloride) 150mg prolonged release tablets (GlaxoSmithKline UK)

Problem / background

There is a supply issue affecting Zyban® (bupropion hydrochloride) 150mg prolonged release tablets caused by a manufacturing site transfer.

It is expected current stock will be depleted week commencing 15th June with resupply anticipated at the end of November 2020.

Zyban® (bupropion hydrochloride) 150mg prolonged release tablets are indicated as an aid to smoking cessation in combination with motivational support in nicotine-dependent patients. It can also be supplied via PGDs.

Zyban® is also used off-label e.g. in treatment resistant depression.

Alternative products

Unlicensed imports

The following specialist importer companies are able to source bupropion 150mg prolonged release tablets (please note there may be other companies that can also source supplies):

- Alium Medical
- Clinigen
- Mawdsleys
- Target Healthcare

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:

- [Prescribing unlicensed medicines](#), General Medical Council (GMC),
- [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency
- [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society

When prescribing a product that is not licensed in the UK prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done by annotating the prescription with the following wording: “**special order**”.

Alternative treatment options

There is no dose equivalence data when switching between Zyban® and other smoking cessation treatments.

- All Champix® (varenicline tartrate) formulations remain available. Pfizer have advised they are able to support an uplift in demand during this time.
- Various nicotine replacement therapies also remain available.

Although Zyban® is rarely prescribed for treatment resistant depression, patients prescribed it for this indication are likely to have previously tried several other anti-depressants and should be referred to their secondary care specialist for individual review if unlicensed supplies are not considered appropriate.

Distribution

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

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| • Chief pharmacists | • Hospital pharmacies |
| • Clinical governance leads | • Hospital pharmacists |
| • Clinical Procurement Specialists | • Medical directors |
| • Community hospitals | • Outpatient clinics |
| • Community nurses | • Pharmaceutical advisors |
| • District nurses | • Pharmacists |

NHS England regional teams

For onward distribution to Community Pharmacists.

General Practice

For onward distribution to all relevant staff including GPs, Practice Managers and Practice Nurses.

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

Enquiries

Send enquiries about this notice to the DHSC Supply Resilience Team, quoting reference number **SDA/2020/010** - Email: supplyresiliencemd@dhsc.gov.uk