

Supply Disruption Alert

SDA/2020/009

Issued: 29 May 2020

Danazol 100mg and 200mg capsules – Supply Disruption

Schedule 4 (CD Anab)

Summary

- Danazol 100mg and 200mg capsules have been discontinued in the UK and remaining supplies of both strengths are now exhausted.
- Danazol has several licensed indications and off-label uses. The management of patients prescribed danazol for licensed indications will differ to those prescribed danazol for an off-label use.
- A limited quantity of unlicensed supplies of danazol 100mg and 200mg capsules have been sourced.

Action

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

For patients prescribed danazol for licensed indications:

- clinicians should not initiate new patients on danazol 100mg and 200mg capsules;
- GPs should identify all patients prescribed danazol for licensed indications and;
 - make early contact with the patient or patient's carer to allow time to plan for any switch strategies;
 - refer to local or national treatment guidelines to switch patients to an alternate licensed therapy [see advice section later]; or
 - make early contact with secondary/tertiary care specialists for advice on management options or referral to specialist.

For patients prescribed danazol for off-label indications:

- clinicians should not initiate new patients on danazol 100mg and 200mg capsules;
- GPs should identify all patients prescribed danazol for an off-label use and;
 - make early contact with the patient or patient's carer to determine the quantity of their remaining supplies;
 - issue a prescription for unlicensed danazol immediately to enable community pharmacies to obtain supplies from specialist importer companies in a timely manner;
 - work with local pharmacies to understand more about the specific unlicensed products that can be sourced and associated lead times; or
 - immediately refer patients to their secondary care specialist for individual review where patients have insufficient supplies to last until the unlicensed supply becomes available or where prescribing unlicensed danazol capsules are not considered appropriate.
- secondary care settings should consider ordering unlicensed supplies of danazol 100mg and 200mg capsules immediately.

Deadlines for actions

Actions initiated: on receipt of this alert
Actions completed: as soon as possible

Product details

Danazol 100mg and 200mg capsules (Mylan)

Problem / background

Sanofi discontinued Danol (danazol) capsules from the UK market in December 2019 and supplies are no longer available. The other manufacturer, Mylan, have identified a problem with the active pharmaceutical ingredient (API) which has led to the discontinuation of danazol capsules within the UK and supplies of both strengths are now exhausted.

There is limited prescribing of danazol for patients using it for licensed indications and for those that are, licensed alternatives are available. There are greater concerns for patients prescribed danazol for off-label indications where fewer treatment options exist and specialist advice indicates that the best long-term option is for patients to be maintained on unlicensed imports of danazol. An overview of licensed and off-label indications is provided below.

Licensed indications:

- Endometriosis.
- Dysfunctional uterine bleeding presenting as menorrhagia. To control excessive blood loss and to control associated dysmenorrhoea.
- For the treatment of severe cyclical mastalgia with or without nodularity (fibrocystic disease) unresponsive to counselling or simple analgesics. To reduce pain, tenderness and nodularity.
- For the control of benign, multiple or recurrent breast cysts in conjunction with aspiration.
- Severe symptomatic gynaecomastia, both idiopathic as well as drug induced
- Pre-operative thinning of the endometrium prior to hysteroscopic endometrial ablation.

Off-Label uses include (but are not exclusive to):

- Short-term treatment of acute attacks and long-term preventative management of hereditary angioedema (HAE)
- A treatment option for the management of myelofibrosis related anaemia.
- The management of immune thrombocytopenia purpura (ITP), as a third or subsequent line treatment option.
- Key therapeutic option for the treatment of cholinergic urticaria.

Advice on switching patients to alternate therapies

National guidance for alternative treatment options to danazol, for its licensed indications:

- **Endometriosis: diagnosis and management**
NICE guideline [NG73]: 06 September 2017: <https://www.nice.org.uk/guidance/ng73>
- **Heavy menstrual bleeding: assessment and management**
NICE guideline [NG88]: 14 March 2018, updated: 31 March 2020:
<https://www.nice.org.uk/guidance/ng88>
- **Breast pain – cyclical**
NICE. Clinical Knowledge Summary, August 2016: <https://cks.nice.org.uk/fibroids#!scenario>
- **Mastitis and breast abscess**
NICE. Clinical Knowledge Summary, October 2018: <https://cks.nice.org.uk/mastitis-and-breast-abscess#!scenario:2>
- **Investigation and Management of Gynaecomastia in Primary & Secondary Care Association of Breast Surgery, June 2019:** <https://associationofbreastsurgery.org.uk/media/65097/abs-summary-statement-gynaecomastia-2019.pdf>

Unlicensed imports

The following specialist importer companies are able to source danazol 100mg and 200mg capsules (please note there may be other companies that can also source supplies):

- Alium Medical
- Durbin PLC
- Clinigen
- Mawdsleys

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 (MHRA)
- [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**”.

Distribution

Trusts (NHS boards in Scotland)

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

- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists
- Community hospitals
- Community nurses
- District nurses
- Hospital pharmacies
- Hospital pharmacists
- Immunologists
- Medical directors
- Outpatient clinics
- Pharmaceutical advisors
- Pharmacists
- Gynaecologists
- Haematologists

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/2020/009 - Email: supplyresiliencemd@dhsc.gov.uk