

Supply Disruption Alert

Danazol 100mg and 200mg capsules

- Danazol 100mg and 200mg capsules have been discontinued in the UK.
- We have a very limited quantity remaining in stock of Danazol 100mg and 200mg.
- 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.

Action

For patients prescribed Danazol for licensed indications:

- Do not initiate new patients on Danazol 100mg or 200mg capsules.
- For patient admitted to hospital on Danazol for licensed indications;
 - Refer to local or national treatment guidelines (see below) to switch patients to an alternate licensed therapy or
 - Make contact with a specialist for the relevant clinical area for advice on management options

For patients prescribed Danazol for off-label indications:

- Do not initiate new patients on Danazol 100mg or 200mg capsules.
- For patients admitted to hospital on Danazol for an off-label indication;
 - Make early contact with the patient or patient's carer to determine the quantity of their remaining supplies.
 - Issue a prescription for Danazol immediately and inform your ward pharmacist to enable early action to secure a supply from remaining limited stock or from specialist importer companies in a timely manner.
 - Pharmacists to communicate with local community pharmacies prior to discharge to ensure continuation of treatment post discharge. OR:
 - Immediately refer to a specialist for the relevant clinical area for review where there are insufficient supplies to last until the unlicensed supply becomes available or where prescribing unlicensed Danazol capsules are not considered appropriate.

Indications and advice on alternatives

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.
- Myelodysplastic syndromes and myeloproliferative disorders.
- Key therapeutic option for the treatment of cholinergic urticaria.

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/breast-pain-cyclical>

- **Mastitis and breast abscess**

NICE. Clinical Knowledge Summary, October 2018: <https://cks.nice.org.uk/mastitis-and-breast-abscess#!scenario:1>

- **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>

For further advice, please contact your ward pharmacist.

Reference

Full alert details can be accessed here:

<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103048>