



Medicine Supply Notification

MSN/2023/067

Topotecan hydrochloride 4mg powder for concentrate for solution for infusion and topotecan (Hycamtin®) 0.25mg and 1mg capsules

Tier 2 – Medium impact*

Date of issue: 18/07/2023

Link: [Medicines Supply Tool](#)

Summary

- Topotecan hydrochloride 4mg powder for concentrate for solution for infusion will be out of stock between mid-July and late August 2023.
- Topotecan (Hycamtin®) 0.25mg capsules are out of stock until end of September 2023
- Topotecan (Hycamtin®) 1mg capsules will be out of stock from end of July 2023 until end of September 2023
- Topotecan hydrochloride **1mg powder for concentrate for solution for infusion** remains available and can support an uplift in demand for topotecan **4mg powder for concentrate for solution for infusion**.
- Topotecan **1mg/1ml and 4mg/4ml solution for injections** remain available but will not be able to support increased demand for either **topotecan 4mg powder for infusion and topotecan capsules**.
- Where the above options are not suitable, unlicensed supplies of topotecan 1mg/1ml and 4mg/4ml solution for injection may be sourced, lead times vary.
- NHS provider trust stock holding may allow for mutual aid between hospitals; local procurement teams should contact Regional Pharmacy Procurement Specialists to discuss if this is possible.

Actions Required

For **topotecan 4mg powder for concentrate for solution for infusion**, NHS provider Trust pharmacy procurement teams and clinical teams should:

- review local stock holding and ensure stock is available for patients already commenced on treatment;
- review chemotherapy scheduling systems to identify all patients due to start treatment with topotecan infusion during the period of shortage;
- only order sufficient stock from established distribution routes to meet actual demand during the period of shortage;
- consider using topotecan hydrochloride **1mg powder for concentrate for solution for infusion** to make up dose if unable to source sufficient volumes of 4mg vials;
- consider placing orders for unlicensed imports if a larger than usual number of patients are scheduled for treatment during the period of shortage; and
- contact Regional Pharmacy Procurement specialist if unable to source both **1mg powder for concentrate for solution for infusion** or unlicensed imports as they may be able to facilitate mutual aid between hospitals.

*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

For **topotecan (Hycamtin®) 0.25mg and 1mg capsules**, where patients have insufficient supply to last until the re-supply date, all healthcare professionals in secondary care who prescribe or dispense topotecan capsules should:

- review local stock holding of topotecan 0.25mg and 1mg capsules and ensure stock is available for all patients already commenced on treatment;
- review chemotherapy patient scheduling systems to identify all patients due to start treatment with topotecan capsules during the period of shortage;
- if unable to source either 0.25mg and 1mg topotecan capsules, contact Regional Pharmacy Procurement specialist who may be able to facilitate mutual aid between hospitals;
- consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below); and
- if the above options are not considered appropriate, advice should be sought from specialists on management options.

Supporting information

Clinical Information

Topotecan intravenous infusion as monotherapy is licensed for the treatment of patients with metastatic carcinoma of the ovary after failure of first-line or subsequent therapy, and for patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate. Topotecan infusion in combination with cisplatin is licensed for treatment of patients with carcinoma of the cervix recurrent after radiotherapy and for patients with stage IVB disease.

For ovarian and SCLC, the recommended dose is 1.5 mg/m² per day for five consecutive days with a three-week interval between the start of each course. If well tolerated, treatment may continue until disease progression. For cervical carcinoma, the recommended dose is 0.75 mg/m²/day on days 1, 2 and 3, with cisplatin administered day 1 following the topotecan dose. This treatment schedule is repeated every 21 days for six courses or until progressive disease.

Topotecan capsules are licensed as monotherapy for the treatment of adult patients with relapsed SCLC for whom re-treatment with the first-line regimen is not considered appropriate. The recommended dose is 2.3mg/m² per day for five consecutive days with a three-week interval between the start of each course. If well tolerated, treatment may continue until disease progression. The capsule(s) must be swallowed whole and must not be chewed crushed or divided.

Please see the following links for further information:

- [BNF topotecan](#)
- [SmPCs: topotecan products](#)

Guidance on ordering and prescribing unlicensed imports

- The following specialist importers have confirmed they can source unlicensed topotecan 1mg/1ml solution for injection (please note there may be other companies that can also source supplies):
 - Mawdsleys
 - Target Healthcare

- The following specialist importers have confirmed they can source unlicensed topotecan 1mg/1ml solution for injection (please note there may be other companies that can also source supplies):
 - Alium
 - Mawdsleys
 - Orifarm
- 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:
 - [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
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC),

* Please note no specialist importers can source unlicensed topotecan capsules

Enquiries

Enquiries from NHS Trusts in England should in the first instance be directed to your Regional Pharmacy Procurement Specialist, who will escalate to national teams if required.

REGION	Full Name	Email
Midlands	Andi Swain	andi.swain@nhs.net
East of England	James Kent	james.kent@nhs.net
London	Jackie Eastwood	jacqueline.eastwood@gstt.nhs.uk
North East and Yorkshire	David Allwood	davidallwood@nhs.net
North West	Richard Bateman	richard.bateman@liverpoolft.nhs.uk
South East	Alison Ashman	Alison.Ashman@berkshire.nhs.uk
South West	Danny Palmer	danny.palmer@uhbw.nhs.uk

Scotland

nss.nhssmedicineshortages@nhs.scot

Wales

MedicinesShortages@gov.wales

Northern Ireland

RPHPS.Admin@northerntrust.hscni.net

All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team quoting reference number MSN/2023/067.

Email: DHSCmedicinesupplyteam@dhsc.gov.uk.