



## **One Wales Medicines Assessment Group Recommendation**

Trametinib (Mekinist<sup>®</sup>) film-coated tablets (OW30)

**Date of advice:** June 2025

**AWTTC reference number:** OW30

**Using the agreed starting and stopping criteria trametinib (Mekinist<sup>®</sup>) can be made available within NHS Wales for the treatment of recurrent low grade serous ovarian carcinoma (LGSOC) which has progressed following at least one previous platinum-based regimen.**

The risks and benefits of the off-label use of trametinib (Mekinist<sup>®</sup>) for this indication should be clearly stated and discussed with the patient to allow informed consent.

Providers should consult the relevant guidelines on prescribing unlicensed medicines before any off-label medicines are prescribed.

There is a simple discount patient access scheme (PAS) for trametinib.

This recommendation has been endorsed by the All Wales Medicines Strategy Group (AWMSG) and ratified by Welsh Government.

This recommendation will be reviewed after 12 months or earlier if new evidence becomes available.

### **Clinician responsibility**

Clinicians will be obliged to collect and monitor patient outcomes. Evidence of clinical outcomes will be taken into consideration when reviewing the One Wales Medicines Assessment Group decision.

### **Health board responsibility**

Health boards will take responsibility for implementing One Wales Medicines Assessment Group decisions and ensuring that a process is in place for monitoring clinical outcomes

**One Wales advice assists consistency of access across NHS Wales and will be disseminated to the service following ratification by Welsh Government.**

Statement of use: No part of this recommendation may be reproduced without the whole recommendation being quoted in full and cited as: All Wales Medicines Strategy Group Advice (OW30): Off-label trametinib (Mekinist®) for recurrent low grade serous ovarian carcinoma June 2025



**AWTTC**

All Wales Therapeutics & Toxicology Centre  
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

## **Starting and stopping criteria for the treatment of recurrent low grade serous ovarian carcinoma (LGSOC) which has progressed following at least 1 previous platinum-based regimen**

These criteria are adapted from the NHS England Clinical Commissioning Policy 2253<sup>1</sup> in collaboration with oncologists in Wales.

### **Starting criteria:**

Patients must satisfy all the following criteria. Treatment may be considered in adults (aged 18 years and above) who:

- have a confirmed diagnosis of LGSOC that is recurrent or progressed following treatment with at least one line of platinum-based chemotherapy
- have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at the time of treatment initiation.
- have not had previous treatment with a MEK inhibitor

A full list of precautions is included in the Summary of Product Characteristics (SmPC)<sup>2</sup>.

Trametinib should always be initiated by an experienced oncologist following a multidisciplinary team (MDT) discussion.

Patients who satisfy the eligibility criteria will be prescribed trametinib following consultation with the patient and/or carer after consideration of potential adverse effects, cautions, contraindications and an explanation of alternative treatment options. This consultation should be recorded in the patient's notes.

Trametinib should be used as monotherapy at a maximum recommended dose of 2 mg orally once daily<sup>2</sup>, as part of a 28-day cycle. Dose reduction(s) may be required down to either 1.5 mg orally once daily or 1 mg orally once daily. This decision should be made following appropriate clinical assessment. Treatment is continued until disease progression or unacceptable toxicity occurs. Recommended modifications to manage adverse reactions are provided in the SmPC<sup>2</sup>.

### **Monitoring:**

- Full blood count
- Urea and electrolytes
- Liver function tests
- Blood pressure
- ECG
- ECHO
- Clinical evaluation of side effects, refer to SmPC

The above tests should be done at baseline. Repeat blood tests and urea and electrolytes prior to each cycle for 3 months then every 3 months thereafter. Repeat liver function tests prior to each cycle for 6 months, then every 3 months thereafter.



# **AWTTC**

All Wales Therapeutics & Toxicology Centre  
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

ECHO at baseline then at one month and then approximately every 3 months. Blood pressure before every cycle. Refer also to local protocols on scheduling tests.

Whilst on treatment a computed tomography (CT) will be performed every 3 months, according to response to treatment.

If patients report new visual disturbances, such as diminished central vision, blurred vision or loss of vision at any time while on trametinib, a prompt ophthalmological assessment is recommended<sup>2</sup>. Symptoms suggestive of interstitial lung disease should be promptly investigated and treatment permanently discontinued<sup>2</sup>.

This list is not exhaustive. Any other monitoring should be in accordance with the SmPC for trametinib<sup>2</sup>.

### Stopping criteria:

- evidence of clinically significant disease progression or symptomatic deterioration as agreed in the MDT
- toxicity; dosing reduction may be considered, follow the guidance in the SmPC.
- patient request

Only one course of treatment may be issued in accordance with this advice. Requests for repeat courses should be explored through funding mechanisms such as the individual patient funding request process.

### Other considerations:

- AWTTTC patient information leaflets on understanding unlicensed medicines in English and Welsh and an easy read format, these can be accessed [here](#).
- It is important that outcomes are collected for this patient cohort and the outcomes will be reviewed by the One Wales Medicines Assessment Group after 12 months.
- Clinicians may wish to use one of the [Cancer Research UK consent forms for SACT \(Systemic Anti-Cancer Therapy\)](#) to help ensure your patient is fully informed when consenting to SACT.
- The Strategic Clinical Network for Cancer standard is that all patients receiving SACT should be given the All Wales Cancer Treatment Alert Card with the treating team being responsible for ensuring that the details of which treatment type and name is clearly indicated on the card and the patient is given supporting information and explanations. Further information can be found here: [Systemic Anti-Cancer Therapies \(SACT\) - NHS Wales Executive](#)

### References

1. NHS England. Clinical commissioning policy. Trametinib in recurrent or progressive low grade serous ovarian cancer (adults). Nov 2023. Available at: <https://www.england.nhs.uk/publication/clinical-commissioning-policy->



# AWTTTC

All Wales Therapeutics & Toxicology Centre  
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

[trametinib-in-recurrent-or-progressive-low-grade-serous-ovarian-cancer/](#).

Accessed May 2025.

2. Novartis Pharmaceuticals UK Ltd. Mekinist®. 2 mg film-coated tablets. Summary of Product Characteristics. Jul 2023. Available at: <https://www.medicines.org.uk/emc/product/5072/smpc>. Accessed May 2025.



**AWTTC**

All Wales Therapeutics & Toxicology Centre  
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan