17 September 2026
EMADOC-1829012207-70505
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sepalna

senaparib

On 17 September 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sepalna, intended for the maintenance treatment of advanced epithelial ovarian, fallopian tube and primary peritoneal cancer.

The applicant for this medicinal product is SFL Pharmaceuticals Deutschland GmbH.

Sepalna will be available as 20 mg hard capsules. The active substance of Sepalna is senaparib, an inhibitor of poly(ADP-ribose) polymerase (PARP) (ATC code: L01XK07) that blocks the repair of damaged DNA in cancer cells and causes the cancer cells to die.

The benefit of Sepalna as maintenance treatment in patients with advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response following first-line platinum-based chemotherapy is an improvement in progression-free survival (PFS) compared with placebo.

The most common side effects with Sepalna are anaemia, leukopenia, neutropenia, thrombocytopenia, nausea, transaminases increased, fatigue, abdominal pain, vomiting, dizziness, diarrhoea, decreased appetite, lymphopenia, upper respiratory tract infection, haematuria, gamma-glutamyltransferase increased, hyperbilirubinaemia, headache, and arthralgia.

The full indication is:

> Sepalna is indicated as monotherapy for the maintenance treatment of adult patients with advanced (FIGO Stages III and IV) epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Treatment with Sepalna should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.