



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 October 2026
EMADOC-1829012207-72049
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Rasonque daraxonrasib

On 15 October 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 Rasonque,² intended as monotherapy for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy.

The applicant for this medicinal product is Revolution Medicines Netherlands B.V.

Rasonque will be available as 100 mg and 150 mg film-coated tablets. The active substance of Rasonque is daraxonrasib, an antineoplastic agent (ATC code: not yet assigned) that inhibits the RAS GTPase family. Daraxonrasib binds to cyclophilin A to form a complex that inhibits RAS signalling by disrupting interactions with downstream effectors, thereby killing cancer cells and slowing cancer growth.

The benefits of Rasonque include longer median overall survival (OS) and median progression-free survival (PFS) compared with standard chemotherapy. The most common side effects are rash, diarrhoea, stomatitis, nausea and vomiting.

The full indication is:

Rasonque as monotherapy is indicated for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy.

Rasonque should be initiated by physicians experienced in the use of anticancer medicinal products.

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.

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

² This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

