# PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

## SUMMARY OF RISK MANAGEMENT PLAN FOR EQUIDACENT (BEVACIZUMAB)

This is a summary of the risk management plan (RMP) for Equidacent. The RMP details important risks of Equidacent, how these risks can be minimised, and how more information will be obtained about Equidacent's risks and uncertainties (missing information).

Equidacent summary of product characteristics (SmPC) and its package leaflet gives essential information to healthcare professionals and patients on how Equidacent should be used.

This summary of the RMP for Equidacent should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European public assessment report (EPAR).

Important new concerns will be included in updates of the Equidacent RMP.

### I. THE MEDICINE AND WHAT IT IS USED FOR

Equidacent is authorised for metastatic carcinoma of the colon or rectum; metastatic breast cancer; advanced metastatic or recurrent non-small cell lung cancer; advanced and/or metastatic renal cell cancer; epithelial ovarian, fallopian tube and primary peritoneal cancer; and cervical cancer (see SmPC for the full indications).

It contains bevacizumab as the active substance and is given as intravenous route.

Further information about the evaluation of Equidacent's benefits can be found in Equidacent's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine webpage.

https://www.ema.europa.eu/en/medicines/human/EPAR/equidacent

### II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MIMIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Equidacent, together with measures to minimise such risks and the proposed studies for learning more about Equidacent's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size – the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status – the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

## II.A LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of Equidacent are risks that need special management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Equidacent. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | None |
| Important potential risks | None |
| Missing information | None |

## II.B SUMMARY OF IMPORTANT RISKS

There are no important risks or missing information for Equidacent.

## II.C POST-AUTHORISATION DEVELOPMENT PLAN

### *II.C.1 STUDIES WHICH ARE CONDITIONS OF THE MARKETING AUTHORISATION*

None.

### *II.C.2 OTHER STUDIES IN POST-AUTHORISATION DEVLOPMENT PLAN*

None.