

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Infusion solutions should be used immediately after dilution. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless the infusion solutions have been prepared in a sterile environment. When dilution has taken place in a sterile environment, Equidacent is stable for 32 days at 2°C to 8°C plus an additional 48 hours at 2°C to 30°C.

Do not use Equidacent if you notice any particulate matter or discolouration prior to administration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Equidacent contains

- The active substance is bevacizumab. Each mL of concentrate contains 25 mg of bevacizumab, corresponding to 1.4 to 16.5 mg/mL when diluted as recommended.
Each 4 mL vial contains 100 mg of bevacizumab, corresponding to 1.4 mg/mL when diluted as recommended.
Each 16 mL vial contains 400 mg of bevacizumab, corresponding to 16.5 mg/mL when diluted as recommended.
- The other ingredients are sodium L-glutamate, sorbitol (E420), polysorbate 80, hydrochloric acid and water for injections.

What Equidacent looks like and contents of the pack

Equidacent is a concentrate for solution for infusion. The concentrate is a clear to opalescent, colourless to pale brownish-yellowish solution in a glass vial with a rubber stopper. Each vial contains 100 mg bevacizumab in 4 mL of solution or 400 mg bevacizumab in 16 mL of solution. Each pack of Equidacent contains one vial.

Marketing Authorisation Holder

Centus Biotherapeutics Europe Limited
South Bank House, Barrow Street
Dublin 4
Ireland

Manufacturer

Pharmaserv Pharma Services Limited
Skybridge House, Corballis Road North, Dublin Airport,
Swords, Co. Dublin, K67 P6K2,
Ireland

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.