

מידע לצוות הרפואי

معلومات للطاقم الطبي

Information for Healthcare Professionals

Opdualag is supplied as a single-dose vial and does not contain any preservatives. Preparation should be performed by trained personnel in accordance with good practices rules, especially with respect to asepsis.

Opdualag can be used for intravenous administration either:

- without dilution, after transfer to an infusion container using an appropriate sterile syringe;
- or
- after diluting according to the following instructions:
 - the final infusion concentration should range between 3 mg/mL nivolumab and 1 mg/mL relatlimab to 12 mg/mL nivolumab and 4 mg/mL relatlimab.
 - the total volume of infusion must not exceed 160 mL. For patients weighing less than 40 kg, the total volume of infusion should not exceed 4 mL per kilogram of patient weight.

Opdualag concentrate may be diluted with either:

- sodium chloride 9 mg/mL (0.9%) solution for injection; or
- 50 mg/mL (5%) glucose solution for injection.

Preparing the infusion

- Inspect the Opdualag concentrate for particulate matter or discoloration. Do not shake the vial. Opdualag is a clear to opalescent, colourless to slightly yellow solution. Discard the vial if the solution is cloudy, discoloured, or contains extraneous particulate matter.
- Withdraw the required volume of Opdualag concentrate using an appropriate sterile syringe and transfer the concentrate into a sterile, intravenous container (ethylvinyl acetate (EVA), polyvinyl chloride (PVC), or polyolefin). Each vial is filled with 21.3 mL of solution, which includes an overfill of 1.3 mL.
- If applicable, dilute Opdualag solution with the required volume of sodium chloride 9 mg/mL (0.9%) solution for injection or 50 mg/mL (5%) glucose solution for injection. For ease of preparation, the concentrate can also be transferred directly into a pre-filled bag containing the appropriate volume of sodium chloride 9 mg/mL (0.9%) solution for injection or 50 mg/mL (5%) glucose solution for injection.
- Gently mix the infusion by manual rotation. Do not shake.

Administration

Opdualag infusion must not be administered as an intravenous push or bolus injection.

Administer the Opdualag infusion intravenously over a period of 30 minutes.

Use of an infusion set and an in-line or add-on filter, sterile, non-pyrogenic, low protein binding filter (pore size of 0.2 µm to 1.2 µm) is recommended.

Opdualag infusion is compatible with EVA, PVC and polyolefin containers, PVC infusion sets and in-line filters with polyethersulfone (PES), nylon, and polyvinylidene fluoride (PVDF) membranes with pore sizes of 0.2 µm to 1.2 µm.

Do not co-administer other medicinal products through the same infusion line.

After administration of the Opdualag dose, flush the line with sodium chloride 9 mg/mL (0.9%) solution for injection or 50 mg/mL (5%) glucose solution for injection.

Storage conditions and shelf life

Unopened vial

Opdualag must be **stored in a refrigerator** (2°C to 8°C). The vials must be kept in the original package in order to protect from light. Opdualag should not be frozen.

The unopened vial can be stored at controlled room temperature (up to 25°C) for up to 72 hours.

Do not use Opdualag after the expiry date which is stated on the carton and the vial label after EXP. The expiry date refers to the last day of that month.

After preparation of infusion

Chemical and physical in-use stability from the time of preparation has been demonstrated as follows (times are inclusive of the administration period):

Infusion preparation	Chemical and physical in-use stability	
	Storage at 2°C to 8°C protected from light	Storage at room temperature (≤ 25°C) and room light
Undiluted or diluted with sodium chloride 9 mg/mL (0.9%) solution for injection	30 days	24 hours (of total 30 days storage)
Diluted with 50 mg/mL (5%) glucose solution for injection	7 days	24 hours (of total 7 days storage)

From a microbiological point of view, the prepared solution for infusion, regardless of the diluent, should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless preparation has taken place in controlled and validated aseptic conditions.