Instructions for Use for Healthcare Professionals
Handling Ultomiris

1- How is Ultomiris supplied?

Each vial of Ultomiris contains 1,100 mg of active substance in 11 mL of product solution.

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

2- Before administration

Dilution should be performed in accordance with good practices rules, particularly for the respect of asepsis.

In the absence of compatibility studies, Ultomiris 1,100 mg/11 mL concentrate for solution for infusion must not be mixed with Ultomiris 300 mg/30 mL concentrate for solution for infusion.

Ultomiris should be prepared for administration by a qualified healthcare professional using aseptic technique.

- Visually inspect Ultomiris solution for particulate matter and discolouration.
- Withdraw the required amount of Ultomiris from the vial(s) using a sterile syringe.
- Transfer the recommended dose to an infusion bag.
- Dilute Ultomiris to a final concentration of 50 mg/mL (initial concentration divided by 2) by adding the appropriate amount of sodium chloride 9 mg/mL (0.9%) solution for injection to the infusion as per the instructions provided in table below.

Table 1: Loading dose administration reference table

Body weight range (kg)[a]	Loading dose (mg)	Ultomiris volume (mL)	Volume of NaCl diluent[b] (mL)	Total volume (mL)	Minimum infusion duration minutes (hours)
≥ 10 to < 20	600	6	6	12	45 (0.8)
≥ 20 to < 30	900	9	9	18	35 (0.6)
≥ 30 to < 40	1,200	12	12	24	31 (0.5)
≥ 40 to < 60	2,400	24	24	48	45 (0.8)
≥ 60 to < 100	2,700	27	27	54	35 (0.6)
≥ 100	3,000	30	30	60	25 (0.4)

[a] Body weight at time of treatment

[b] Ultomiris should only be diluted using sodium chloride 9 mg/mL (0.9 %) solution for injection

Table 2: Maintenance dose administration reference table

Body weight range (kg)[a]	Maintenance dose (mg)	Ultomiris volume (mL)	Volume of NaCl diluent[b] (mL)	Total volume (mL)	Minimum infusion duration minutes (hours)
≥ 10 to < 20	600	6	6	12	45 (0.8)
≥ 20 to < 30	2,100	21	21	42	75 (1.3)
≥ 30 to < 40	2,700	27	27	54	65 (1.1)
≥ 40 to < 60	3,000	30	30	60	55 (0.9)
≥ 60 to < 100	3,300	33	33	66	40 (0.7)
≥ 100	3,600	36	36	72	30 (0.5)

[a] Body weight at time of treatment

[b] Ultomiris should be only diluted using sodium chloride 9 mg/mL (0.9 %) solution for injection

- Gently agitate the infusion bag containing the diluted Ultomiris solution to ensure thorough mixing of the medicinal product and diluent. Ultomiris should not be shaken.
- The diluted solution should be allowed to warm to room temperature (18 °C–25 °C) prior to administration by exposure to ambient air during approximately 30 min.
- The diluted solution must not be heated in a microwave or with any heat source other than the prevailing room temperature.
- Discard any unused portion left in a vial as the medicinal product contains no preservatives.
- The prepared solution should be administered immediately following preparation. Infusion must be administered through a 0.2 µm filter.
- If the medicinal product is not used immediately after dilution, storage times must not exceed 24 hours at 2 °C–8 °C or 5 hours at room temperature taking into account the expected infusion time.

3- Administration

- Do not administer Ultomiris as an intravenous push or bolus injection.
- Ultomiris should only be administered via intravenous infusion.
- The diluted solution of Ultomiris should be administered by intravenous infusion over approximately 45 min using a syringe-type pump or an infusion pump. It is not necessary to protect the diluted solution of Ultomiris from light during administration to the patient.

The patient should be monitored for one hour following infusion. If an adverse event occurs during the administration of Ultomiris, the infusion may be slowed or stopped at the discretion of the physician.

4- Special handling and storage

Store in a refrigerator (2 °C–8 °C). Do not freeze. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after ‘EXP’. The expiry date refers to the last day of that month.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.