STATEMENT

RE: PIXUVRI – Declaration of weight of excipients and stability

Date: March 14th, 2022

Les Laboratoires Servier (LLS) as the market authorization holder for Pixuvri declares the composition of each vial of product as follows :

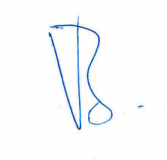
Composition of Pixuvri

Component	Quantity per vial (mg)
Pixantrone Drug Substance	29 mg of pixantrone equivalent to 50 mg of pisantrone dimaleate
Sodium Chloride	100 mg[a]
Lactose monohydrate	300 mg
Sodium Hydroxide 1N	0.135 ml
Hydrochloric Acid 1N	0.135 ml
Water for Injections	QS[b]

[a] *Includes the amount (7,5 mg) generated by the HCI/NaOH neutralisation*

[b] *The majority of Water for Infections is removed during lyophilization*

The product is stable when stored at 2-8°C in outside carton protected from light for up to the expiration date printed on the label. From a microbiological point of view, the product should be used immediately upon reconstitution. 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 reconstitution and dilution have taken place in controlled and validated aseptic conditions. Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature (15°C to 25°C) and daylight exposure in polyethylene (PE) standard infusion bags. Pixuvri vials are intended for single use only and any remaining product upon use should be discarded.



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