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NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

04.02.2020	Rote-Hand-Brief zu Ecalta: Infusionslösung darf nicht eingefroren werden

	Wirkstoff Anidulafungin Der Zulassungsinhaber Pfizer Pharma PFE GmbH informiert, dass entgegen der Angaben in der aktuellen Produktinformation die rekonstituierte Infusionslösung nicht eingefroren werden darf. Die Infusionslösung kann bei 25 °C über 48 Stunden aufbewahrt werden. Durch das Einfrieren und nachfolgende Auftauen des Produktes kann es aufgrund einer mangelnden Löslichkeit des Wirkstoffes zur Bildung von sichtbaren Partikeln in der Infusionslösung kommen. Die Produktinformation zu Ecalta wird entsprechend aktualisiert.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 9th 2020.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since January 24th 2020.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.