

Tourcoing, 6th of February, 2020

Field SAFETY NOTICE

Field Safety Notice (FSN) relative to the use of the Macopharma ECP
MACOGENIC SET : XU8501Q-XUV8501QR

Macopharma reference: DEV-2019-01552

ANSM reference: **R2001275**

Dear Sir or Madam

We are writing to inform you that Macopharma has decided to raise a field safety notice (FSN) regarding the current procedure for Extracorporeal Photopheresis (ECP) when performed at the bedside using Macopharma products.

In order to perform an ECP procedure at bedside, and therefore be exempt from the current good cellular therapy practices, we request that all centers whose ECP installation is currently at the bedside to implement the following instructions without delay:

- Transfer cells from the sample bag to the irradiation bag through a sterile connection.
- Perform quality checks to ensure that there is no bacteriological contamination of the re-injected products.
- If necessary, give a feedback on the difficulties faced.
- Give us a feedback on the implementation of these measures within 15 days.

We would like to clarify that the use of our bedside ECP system is based on section L.1211-8 of the Public Health Code. According to this text, elements and products of the human body collected and used for autologous therapeutic purposes in the context of a single medical intervention, not otherwise preserved or prepared, are not subject to laboratory preparation requirements for cell therapy

Our sales and marketing team is at your disposal for any request for new field training.

ANSM has been notified of this safety information.

Please complete the attached form for our records, indicating that you have received this FSN and that it has been distributed within your institution.

Please don't hesitate to contact us if you require any further information or clarification

Laurent PENCHINAT
Head pharmacist

Béatrice CARVALHO
Complaints & Vigilance MD Manager

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Acknowledgment of receipt to fax upon receipt of the FSN or by e-mail	
E-mail	cellule.materiovigilance@macopharma.com
Fax	+33 3 20 11 84 90
Delay	15 days

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FSN date	6 th of February, 2020

<input type="checkbox"/> We confirm receipt of the Field Safety <input type="checkbox"/> We confirm implementation of the measures within 15 days.	
Healthcare Organisation Name	
Organisation Address	
Contact name and Function	
Telephone	
Date and Signature	