

Unavailable medicinal product

Last updated on 2018-05-30

Name	SOPP-SSPP 4 %
Active substance(s)	Human protein plasma solution
Dosage and pharmaceutical form	4 %, solution for infusion
Pack size(s) and dosage	100 ml 4 % 400 ml 4 %

Authorisation holder

Name	CAF-DCF bvba-sprl
Contact information	Avenue de Tyraslaan 109 1120 BRUSSELS

Additional information about the unavailability

Start date	2018-03-30
Expected end date	2018-07-01
Reason unavailability	Technical problems

Due to a production problem encountered by the manufacturer, the medicinal product SOPP-SSPP 4 % (CAF-DCF) is unavailable.

Given this current unavailability in Belgium and the absence of an alternative, the only possibility is to import albumin 5 % in accordance with Article 105 (doctor's statement) of the Royal Decree of 14 December 2006.

The FAMHP (Federal Agency for Medicines and Health Products), INAMI (Belgian national institute for health and disability insurance) and the SPF SPSCAE (Federal Public Service for Public Health, Food Chain Safety and Environment) underline that any such import must be reasonable and that, consequently, only a limited number of products may be imported at one time, to compensate for the unavailability for a maximum duration of two weeks, on condition that there is no available alternative.

A batch of SOPP-SSPP 4 % should be released at the end of May 2018. Based on the current sales figures from CAF-DCF, this supply would ordinarily be enough to last two weeks, but when the numerous pending orders are taken into account, it will be out of stock more quickly. According to the information available, the problem should be resolved by 1 July 2018.

In order to find a short-term solution to the interrupted supply of essential medicinal products, a Task Force may be set up within the unavailabilities working group. To handle the interrupted supply of SOPP-SSPP 4 % as well as possible, the Task Force has come up with the following recommendations:

- Taking into account the limited quantity of stock that should become available at the end of May 2018, it is highly recommended that albumin be used as rationally as possible. In other words, only for plasmapheresis, an indication for which there is no alternative.
- For other more common indications, in particular burns and use in intensive care departments, the use of albumin 20 % is temporarily recommended. According to available information, this medicinal product is available in sufficient quantities.

The FAMHP, INAMI and FPS SPSCAE are still looking for other (less costly) alternatives.