



## **LIPOSTABIL® - Questions and Answers**

**Synonyms:** Lipodissolve, Flabjab, Fat-Away, Lipo-melt

**Active Ingredient:** Phosphatidylcholine

**Q Has the MHRA determined Lipostabil® to be a relevant medicinal product?**

**A** Yes

**Q Is this product licensed in the UK?**

**A** No

**Q Is this product licensed elsewhere?**

**A** Yes, Germany, for example

**Q What is Lipostabil®?**

**A** Lipostabil® is an intravenous preparation of phosphatidylcholine.

**Q What is Lipostabil® licensed for in its country of origin?**

**A** For prevention (prophylaxis) and treatment (therapy) of blood vessel blockages by fat particles (fat embolism).

**Q What about cosmetic use for fat reduction?**

**A** It is not licensed for this use in its country of origin. The product's safety has therefore not been assessed for this indication. Cosmetic use does not constitute a special (clinical) need under SI 1999/4.

**Q Has the product been assessed for safety for cosmetic use?**

**A** The safety has not been established for cosmetic use. The usual route of administration for cosmetic use is subcutaneous. This is specifically warned against in the manufacturer's information sheet.

**Q Surely, subcutaneous use for cosmetic treatments is safer than IV use for the licensed indication?**

**A** The product information sheet from the manufacturer specifically states that Lipostabil® should not be given subcutaneously (injection under the skin).

The company has not studied the safety or efficacy of Lipostabil® when injected subcutaneously. Accordingly, Sanofi-Aventis cannot support the use of the product except for approved indications. Additionally, the statement that subcutaneous use for cosmetic treatments is safer than IV use for the licensed indication may not be accurate, as there are no data to support this statement.

**Q What are the reasons from Sanofi-Aventis for not using Lipostabil® (subcutaneous) for cosmetic purposes in fat removal / reduction?**

**A** It is for the company to make decisions about product development. Sanofi-Aventis has not conducted clinical trials with Lipostabil® via subcutaneous injection for fat removal/reduction, and does not support the off-label use of the product. There are no safety or efficacy data on the use of Lipostabil® for local fat reduction via subcutaneous injection.

**Q Why is this product banned by the MHRA?**

**A** The product is not “banned”.

The MHRA will, however, object to notifications for importation of Lipostabil® for cosmetic purposes. These do not constitute a special (clinical) need, i.e. they are not a medical indication. The product’s safety has not been established for cosmetic use. The usual route of administration for cosmetic use is subcutaneous. This is specifically warned against in the manufacturer’s information sheet.

**Q Are there any known adverse reactions to cosmetic treatment with Lipostabil®?**

**A** The MHRA is aware of at least three potential adverse reactions to cosmetic treatment with Lipostabil® in the UK.

**Q Is this product licensed anywhere for cosmetic use?**

**A** No

**Q Are there any other safety concerns with Lipostabil®?**

**A** The product is based upon soya bean extracts and also contains benzyl alcohol. There may therefore be allergy or sensitivity issues in some patients.

**Q What are the regulations governing importation of unlicensed medicines into the UK?**

**A** Importation of any medicinal product NOT licensed in the UK must be in compliance with The Medicines (Standard Provisions For Licences And Certificates) Regulations 1971 (SI 1971, No. 972) as amended. This provides for import from elsewhere in the EU only by holders of Wholesale Dealers Licences (WL), or from outside of the EU by holders of Wholesale Dealers Import Licences (WI), of products where a special (clinical) need exists and where the MHRA has not objected to the import following notification in accordance with the SI.

The quantities permitted per notification are: 25 individual doses, or sufficient material for 25 patients in a 3 month period. Following receipt, the MHRA has 28 days to assess notifications.

Interim guidelines may be found at:

<http://www.mhra.gov.uk/home/groups/is-md/documents/websiteresources/con009280.pdf>

SI 1999/4 may be found at:

<http://www.hmsso.gov.uk/si/si1999/19990004.htm>

A submission form for unlicensed import notifications may be found at:

[http://www.mhra.gov.uk/home/idcplg?IdcService=GET\\_FILE&dDocName=CON026413&RevisionSelectionMethod=Latest](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON026413&RevisionSelectionMethod=Latest)

**Q Can Lipostabil® be imported for clinical uses in indications such as fat embolism?**

**A** Yes, subject to compliance with the provisions of SI 1999/4 and favourable assessment by the MHRA.

**Q Can Lipostabil® be imported for special (clinical) needs in indications other than fat embolism?**

**A** Possibly, subject to compliance with the provisions of SI 1999/4 and favourable assessment by the MHRA. Such assessment is on a case by case basis.

**Q I have heard that Lipostabil® can be supplied from Guernsey to doctors for administration to their individual patients without the need to notify under SI 1999/4. Is this true?**

**A** This is not correct: the importer must hold the relevant Wholesale Dealer's Licence and must comply with the provisions of SI 1999/4, which include a requirement to notify the MHRA.

**Q How do I obtain cosmetic treatment with Lipostabil®?**

**A** As the MHRA will object to importation of Lipostabil® for cosmetic purposes, this treatment should not be available in the UK

**Q I have seen Lipostabil® advertised for fat reduction- what is the situation with this?**

**A** Unlicensed medicines may not be advertised in the UK and Lipostabil® should not be imported for cosmetic purposes. The MHRA will investigate cases where either activity appears to have taken place, and may take regulatory action.

**Q Why can I not complete my course of cosmetic treatment?**

**A** Lipostabil® is a licensed medicine in its country of origin (Germany) and will have been assessed for safety, quality and efficacy for specific uses (indications) as part of the licensing procedure. The indications for Lipostabil® only relate to specific clinical conditions, such as fat embolism.

Additionally, it should be noted that the safety of Lipostabil® in cosmetic use is not established and would not have been assessed in granting the licence for other indications. The usual route of administration for cosmetic use is subcutaneous. This is specifically warned against in the manufacturer's information sheet.

The MHRA therefore has concerns about the safety of this product in indications not related to those for which it was assessed and licensed in its country of origin.

**Q What should I do if I suspect this treatment has affected me adversely**

**A** You should speak to your GP and ask them to complete a yellow card which will report the adverse reaction to the MHRA, or alternatively you can submit a report directly to the MHRA using the Yellow Card Scheme website address [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk).

**Q Can I bring this product in for my own personal use?**

**A** The regulations does not prohibit individuals from bringing in Lipostabil® for their own personal use. However, the MHRA does have concerns about the safety of this product when administered subcutaneously. Also, the product should not be stored above 8°C. Control of the distribution network from manufacturer to end user, including storage by the end user, is of major importance in ensuring the quality of medicines. Recommendations concerning storage temperatures given on product labels and in product literature are made to ensure optimum stability of products to which they relate in order to help to ensure that they remain safe and effective. Storage and transportation of medicines at temperatures above those recommended increases their rate of degradation. This results not only in reduced effectiveness, but may also result in increased toxicity.

**Q If I bring this product into the UK, can I give it to anyone else?**

**A** Someone who personally imports Lipostabil® for his own use may give it to someone else, but only to enable that person to assist in administering the product to him. You cannot supply the product to another person, if he (i.e. the person to whom you supply it) wishes to use the product himself or if he wants to supply it or administer it to another person.

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