LIPOSTABIL® - Questions and Answers

Active Ingredient: Phosphatidylcholine

Also known as: Lipodissolve, Flabjab, Fat-Away, Lipo-melt

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

A Yes, the MHRA considers that Lipostabil is a relevant medicinal product within the meaning of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, as amended (S.I. 1994/3144).

Q **Does the product have a Marketing Authorisation (sometimes referred to as a product licence)in the UK?**

A No.

Q **Can a medicinal product be imported, supplied or used in the UK without a marketing authorisation?**

A. Yes, if it is either imported for personal use (discussed below) or if it is exempt from the requirement to have a marketing authorisation by regulation 3(2) and paragraph 1 of Schedule 1 to SI 1994/3144. The exemption is limited to products which fulfil a **clinical** need. Where such a product is supplied by wholesale dealing, further conditions may apply under regulation 11 of and Schedule 4 to the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789). In particular, importers of such products must provide MHRA with prior notification of import. Importation will only be permitted where the relevant conditions in Schedule 1 to SI 1994/3144 and Schedule 4 to SI 2005/2798 are met.

Importers from elsewhere in the European Economic Area (EEA) must be holders of Wholesale Dealers Licences (WL), those from outside the EEA must be holders of Manufacturer's Licences, (ML) (previously Wholesale Dealers Import Licences WI, now being updated to Manufacturer's Licences.

Q **Does the product have a marketing authorisation elsewhere?**

A Yes, in Germany.

Q What is Lipostabil®?

A Lipostabil® is a preparation of phosphatidycholine for intravenous use.

Q What use is Lipostabil® authorised 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 authorised for this use.

Q Is this product authorised anywhere for cosmetic use?

A No.

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

A The product's safety for cosmetic use would not have been assessed as part of the application for a marketing authorisation for treatment of fat embolism. The usual route of administration for cosmetic use is subcutaneous. This is contraindicated (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 Surely, subcutaneous use for cosmetic treatments is safer than IV use for the licensed indication?

A The product information sheet from the manufacturer specifically contra-indicates subcutaneous injection of the product (injection under the skin). Therefore, MHRA has particular concerns about its safety in cosmetic use.

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 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.

Q Why is this product banned by the MHRA?

A The MHRA has not banned the product. The manufacturer has not applied for a marketing authorisation in the UK.

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

A The regulations do not prohibit individuals from importing Lipostabil® for their own personal use. However, you should be aware that 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. For example, storage and transportation of medicines at temperatures above those recommended, can increase their rate of degradation. Failure to adhere to such requirements may result not only in reduced effectiveness, but also in increased toxicity.

MHRA considers that if a doctor is involved in, for example, recommending a supplier, assisting in ordering or storing the medicinal product, the product cannot be regarded as imported for personal use.

Q If I import this product for personal use into the UK, can I lawfully give it to anyone else?

A Someone who personally imports Lipostabil® for his own use may give it to someone else in certain limited circumstances, e.g. a family member. Determination of whether importation is for personal use will depend on the particular factual circumstances and is ultimately a matter for the courts.

Q I have seen Lipostabil® advertised in the UK - what is the situation with this?

A Unlicensed medicines may not be advertised or marketed in the UK. In addition, it is not lawful to advertise a prescription only medicine to the public. Lipostabil is a prescription only medicine. The MHRA will investigate cases where either activity appears to have taken place, and may take regulatory action.

Advertising includes every form of advertising, whether in a publication, or by the display of any notice, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other document, or by words inscribed on any article, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting or television, or in any other way, and any reference to the issue of an advertisement shall be construed accordingly

Further information:

The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789).

http://www.opsi.gov.uk/si/si2005/20052789.htm

The Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, as amended (S.I. 1994/3144)

http://www.opsi.gov.uk/si/si1994/Uksi_19943144_en_1.htm

Guidance Note 14

http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007547.pdf

and the section on importation of unlicensed medicines on the MHRA website at http://www.mhra.gov.uk

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