

# PRESS RELEASE

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**Subject:** Consumer Warning – Lipostabil®



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## **Lipostabil® not licensed for cosmetic use**

Lipostabil®, also marketed as Flabjab™, Lipomelt, Liposdissolve and Fat-Away, is being unlawfully advertised in the UK as a cosmetic product for the reduction of fat.

Lipostabil® is licensed as an intravenous medicine in Germany, its country of origin, for the prevention and treatment of blood vessel blockages by fat particles (fat embolism). It is not approved or licensed for cosmetic use. Product safety has not been established for subcutaneous use for cosmetic purposes. Consumers should be aware of this should they be offered the product.

The Medicines and Healthcare products Regulatory Agency (MHRA) has received three reports of potential adverse reactions to cosmetic treatment with Lipostabil®. Some patients may experience allergic reactions or sensitivity issues to the product. The usual route of administration for cosmetic surgery is subcutaneous (injection under the skin) and this is warned against in the manufacturer's information sheet which specifically states that Lipostabil® should **not** be given subcutaneously.

Lipostabil® is not licensed in the UK. However, it may be imported into the country by doctors for clinical use for the prevention and treatment of fat embolism subject to compliance with the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations (SI 1999/4). This allows for importation from elsewhere in the EU by holders of Wholesale Dealers Licences, or from outside of the EU by holders of Wholesale Dealers Import Licences. When ordering, proof must be available from the doctor to demonstrate the existence of a special clinical need for the patient. The MHRA must be consulted about the import by the wholesaler using the notification procedure set out in SI 1999/4. The use of Lipostabil® for cosmetic purposes does not constitute a special clinical need.

Unlicensed medicines may not be advertised in the UK and Lipostabil® should not be imported for cosmetic purposes. The MHRA has concerns about the safety of this product for cosmetic use and continues to investigate a number of cases where medicines legislation may have been breached.

**ENDS**

## **Notes to Editors**

Interim Guidelines on the Import & Supply of Unlicensed Relevant Medicinal Products:  
<http://medicines.mhra.gov.uk/ourwork/licensingmeds/exemptions/interimguide.pdf>

Statutory Instrument (SI 1999/4):  
<http://www.hmsso.gov.uk/si/si1999/19990004.htm>

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