

## **Personal Import of WockhardtUK Ltd bovine and porcine insulins into the United States**

The FDA may permit you to import beef or pork insulin into the United States for your personal use if your diabetes can **not** be treated with human insulin or analogues.

This guide has been written to help you if you have not been able to find a suitable replacement for porcine or bovine insulin in the United States and wish to obtain these insulins from WockhardtUK Ltd.

Although Wockhardt's bovine and porcine insulins have been approved and used in the United Kingdom and other countries for the last 25 years, they are not approved for use in the United States. Therefore, WockhardtUK Ltd cannot supply insulin to you as a U.S. resident until you have received permission from the relevant U.S. authorities to bring the insulin into the United States.

This is what to do:

### **1. Contact the U.S. Department of Agriculture (USDA)**

Because WockhardtUK Ltd insulins are derived from cows or pigs you need permission from the United States Department of Agriculture to bring WockhardtUK Ltd insulins into the country. An "Application for Permit to Import Controlled Material or Transport Organisms or Vectors is required and a simplified form is currently available by request from our Export Dept. (Phone +44 1978 669201, +44 1978 669275, Fax +44 1978 661262 or Email [export@wockhardt.co.uk](mailto:export@wockhardt.co.uk)). Fill in the blank spaces marked with stars, and send it along with your application fee of \$94.00 for a 5 year permit to: (renewals fee = \$61.00/5 years) Note these charges may vary according to the USDA requirements.

U.S. Department of Agriculture  
Animal and Plant Health Inspection Service  
Veterinary Services  
National Center for Import-Export Products Program  
Riverdale MD 20737 1231  
Tel (301) 734-3277

The USDA will send you an official import permit.

### **2. Contact WockhardtUK Ltd**

Personal importation of small amounts of unapproved medicines under specific circumstances may be allowed at the discretion of the U.S. Food and Drugs Administration (FDA). You need to send some documents to WockhardtUK Ltd when you order your insulin so that FDA officials can release your insulin when it arrives in the US. WockhardtUK Ltd will enclose a copy of these documents with your shipment of insulin for the FDA officials to look at when it arrives in the U.S.

These are the documents you should send to WockhardtUK Ltd:

1. A copy of the USDA import permit (see section 1 above)
2. A completed order form (attached)

3. A Recently dated letter from your U.S. licensed practitioner saying that your diabetes can not be treated with human insulin or analogues and that the insulins available in the U.S. do not effectively control your diabetes and are therefore unacceptable.

4. A 'Compassionate Use/ Named Patient Supply: Drug Safety (Pharmacovigilance) Agreement for Hypurin Insulin' completed by the licensed practitioner responsible for the treatment of your diabetes.

**Note: Communication regarding technical or medical aspects of Hypurin insulin or its use.**

*The Company must ensure that the patient communicates directly with and obtains all advice on his or her diabetes treatment from the physician responsible for treatment of his or her diabetes.*

- The Company can not communicate directly with the patient regarding technical or medical aspects of Hypurin insulin or its use.
- The patient must direct all enquiries of this nature to the physician responsible for treatment of his/her diabetes.
- Contact with the Company on matters of this nature must be made by the physician responsible for treatment of the patient's diabetes.
- Communication received by the Company directly from the patient, will be forwarded within two working days of receipt, to the physician responsible for treatment of the patient's diabetes.

5. A Recently dated statement, signed by you, saying that the insulin is for your own personal use and that the number of vials being ordered is no more than six months supply. (Include your name, address, telephone and fax number if you have one, on this statement.)

Please send the above (fax or post) to:

Export Department  
WockhardtUK Ltd  
Ash Road North  
Wrexham Industrial Estate  
Wrexham, LL13 9UF  
United Kingdom

Telephone Number: + 44 1978 669201 or + 44 1978 669275

Fax Number: + 44 1978 661262

Email: [export@wockhardt.co.uk](mailto:export@wockhardt.co.uk)

**Please note that WockhardtUK Ltd cannot supply you with insulin without these five documents.**

**It is also important to note that once we have despatched your insulin, release of this product to you is entirely at the discretion of the U.S. authorities; WockhardtUK Ltd cannot guarantee that the authorities will allow all shipments through. WockhardtUK Ltd can take no responsibility for delay, loss, damage or improper storage of your insulin in transit. However, we will do our best to ensure you get the insulin you need.**

**ORDER FORM FOR WOCKHARDTUK LTD PORK INSULIN VIALS**

PRODUCT	QUANTITY (please indicate)	Cost	TOTAL (please calculate)
Hypurin® Porcine Neutral 100iu 10ml vial		£30.00	
Hypurin® Porcine Isophane 100iu 10ml vial		£30.00	
Hypurin® Porcine Mix 30/70 100iu 10ml vial		£30.00	
+ TNT Courier Cost (2 day service) (up to 40 vials)	1	£130.00	£130.00
<b>Administration Charge</b>		<b>£115.00</b>	<b>£115.00</b>
<b>VAT for European countries only 17.5%</b>			
<b>TOTAL AMOUNT PAYABLE</b>			

**PAYMENT (Please tick choice)**

a)  **By Credit Card**

Please charge my:

- i.  Visa
- ii.  Mastercard
- iii.  Access
- iv.  Eurocard

Card Number

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Expiry Date: \_\_\_/\_\_\_/\_\_\_

Cardholders Name (as shown on the card): .....

Cardholders Address: .....

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.....

I authorise you to debit my credit Account with the above amount.

Signed..... Date.....

b)  **By Banker's Draft - drawn on a U.K Bank (your local Bank should be able to arrange this)**

I enclose a Banker's Draft in Pounds Sterling payable to Wockhardt EU Operations (Swiss) AG (CP Pharmaceuticals is a wholly owned subsidiary of Wockhardt UK Holdings Ltd)

**DELIVERY DETAILS**

These details are *extremely* important, as the insulin will need to be refrigerated immediately upon receipt.

Delivery Address: .....

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Contact Name: .....

Telephone Number: ..... Fax Number: .....

**Please return this form (fax or post) to:**

Export Department  
 WockhardtUK Ltd  
 Ash Road North  
 Wrexham Industrial Estate  
 Wrexham, LL13 9UF  
 United Kingdom  
 Telephone Number: + 44 1978 669221  
 Fax Number: + 44 1978 661262  
 Email: export@wockhardt.co.uk