

**Compassionate Use/ Named Patient Supply:
Drug Safety (Pharmacovigilance) Agreement for Hypurin Insulin**

Supply of Hypurin insulin to the patient is conditional upon completion of this Drug Safety (Pharmacovigilance) Agreement (referred to below as the Agreement).

To be completed by the physician

The Agreement

- This Agreement must be completed by the physician responsible for treatment of the patient's diabetes (referred to below as 'the physician').
- Submission by the physician of a newly completed and signed Agreement will be required each time an order for Hypurin insulin is placed by the patient. The patient refers to the applicant requesting supply of Hypurin insulin.
- The physician must inform the Company, within five working days of the change occurring, if the care of the patient's diabetes is transferred to another physician.
- In the event of the care of the patient's diabetes transferring to another physician, the other physician will also be required to complete and submit an Agreement.

Adverse drug reactions (ADRs)

Wockhardt UK Limited (the Company) must comply with pharmacovigilance legislation which includes ADR reporting and monitoring of the risk-benefit balance of its products.

- The physician must report to the Company any ADRs experienced by the patient that are considered by the physician to be caused by Hypurin insulin.
- The ADR report must be submitted to the Company within five working days of the physician becoming aware of the ADR.
- Details of the ADR/s must be submitted to the Company using Form 1 (page 3 of this Agreement). Form 1 should be completed by the physician and should be faxed or emailed to the Company.
Fax: 00 44 1978 661 702, email: drug.safety@wockhardt.co.uk.

Communication with the patient

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

- 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.

Continued supply of Hypurin insulin

The Company is obliged to monitor and act accordingly in the event of an unfavourable risk-benefit balance.

- The Company reserves the right to cease supply of Hypurin insulin if there is evidence indicating that the risk-benefit balance is unfavourable for the patient.
- Supply of Hypurin insulin will cease if the terms of this Agreement are not fulfilled.

To be completed by the physician, a copy retained by the physician and the original returned to the Company.

I, the undersigned, undertake responsibility for the administration and safe use of Hypurin insulin in
_____ (please enter patient's full name).

I confirm that the patient is unable to tolerate any form of human insulin or analogue and therefore can not be treated with human insulin or with analogues. I am aware that the FDA will only consider the importation of bovine or porcine insulin (including Hypurin) for patients who can not be treated with human insulin or analogues.

Physician's details:
(* mandatory fields)

* Name: _____

* Title (for example, Senior Endocrinologist): _____

* Full postal address: _____

* Telephone number: _____

* Fax and / or email address(both where available):

Fax: _____

Email: _____

Hospital/clinic web site address: _____

Deputy/locum physician in absence of physician: _____

* Physician's signature: _____

* Date: _____

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 Fax: 00 44 1978 661 702, email: drug.safety@wockhardt.co.uk.

SUSPECTED ADVERSE DRUG REACTION REPORT
 COMPASSIONATE USE/NAMED PATIENT SUPPLY

Please note dates in dd/mm/yyyy format

PATIENT DETAILS	Patient Initials: _____	Sex: M / F	Weight if known (kg) _____
Age (at time of reaction): _____		Identification number (Practice / Hospital Ref) *: _____	

SUSPECTED DRUG(S) Give brand name, Product Licence (PL) number and batch number of the drug if known					
	Route	Dosage	Date started	Date stopped	Prescribed for
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

SUSPECTED REACTION/S
Please describe the reaction/s and any treatment given:

Country in which reaction occurred: _____

Outcome: Recovered Recovering Continuing Other

Date reaction/s started: _____ Date reaction/s stopped: _____

Do you consider the reaction to be serious? Yes / No If yes, please indicate why the reaction is considered to be serious :
 [Please note the distinction between serious and severe, for example, a severe headache that is not be life threatening would not generally be considered to be serious. ‘Serious’ classification should be judged on what happened to the patient and not on what might have happened if other circumstances had differed.]

Patient died due to reaction <input type="checkbox"/>	Involved or prolonged inpatient hospitalisation <input type="checkbox"/>
Life threatening <input type="checkbox"/>	Involved persistent or significant disability or incapacity <input type="checkbox"/>
Congenital abnormality <input type="checkbox"/>	Medically significant (please provide details): _____

Was the reaction caused by the drug/s specified above: Definitely Possibly Unlikely

OTHER DRUGS (including self-medication & herbal remedies)
 Did the patient take any other drugs in the last 3 months prior to the reaction? Yes No
 If yes, please give the following information if known:

Drug (Brand, if known)	Route	Dosage	Date started	Date stopped	Prescribed for
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Additional relevant information e.g medical history, test results, known allergies, rechallenge (if performed), suspected drug interactions. For congenital abnormalities please state all other drugs taken during pregnancy and the date of the last menstrual period.

PHYSICIAN REPORTER DETAILS (Name, job title and Professional Address:)

Country: _____ Speciality: _____
Post/zip code: _____ Tel no: _____ Fax no: _____
Email address: _____ Signature: _____ Date: _____

*This is to enable identification the patient in any future correspondence concerning this report.

Please attach additional pages if necessary.