



## INSULIN PRODUCTS

### The Issue

Animal-sourced and biosynthetic (man-made) human insulins are used worldwide for managing diabetes. Recently, some concern has been expressed about the overall safety of insulins and the availability of animal-sourced insulins for those patients who cannot manage their disease using biosynthetic insulin.

### Background

Two types of insulin may be used in the management of diabetes: animal-sourced insulin and biosynthetic human insulin. Historically, preparations of beef, pork, and combined beef-pork insulin were used for managing diabetes. These animal-sourced insulins have been used safely for many years. With the exception of beef-pork insulin, which is no longer available, they are still being used safely today.

The first genetically engineered human insulin (also called biosynthetic human insulin, recombinant, or DNA-derived insulin) was manufactured by Eli Lilly Canada and authorized for the Canadian market in 1983. In 1993, another biosynthetic human insulin made by Novo Nordisk entered the market. Prior to being authorized for sale in Canada, these products were thoroughly reviewed for their effectiveness, safety, and quality. Since then, human biosynthetic insulin has been shown to be safe and effective for treating type I and II diabetes.

With advances in these new types of insulin products, the demand for animal insulins has declined. Manufacturers have responded by focussing on the production and sale of their recombinant or biosynthetic human insulins.

Although the majority of patients with diabetes now use human insulin, there are a small number of patients who cannot manage their disease with these biosynthetic insulins. They need animal-sourced insulin to manage their diabetes and they are concerned about the uninterrupted availability of animal-sourced insulin for the future.

Health Canada does not have the authority to require a manufacturer to make or sell any particular

product. However, within the limits of its mandate, Health Canada continues to work with manufacturers and special interest groups to support the availability of animal-sourced insulins in Canada.

### Insulin Availability

In addition to the original human biosynthetic insulins, newer biosynthetic insulin products are now available, including fast-acting insulin and basal or long-acting insulin. These new versions provide more choice when determining the most appropriate insulin to use.

There are concerns that some healthcare professionals may not be aware that animal-sourced insulins, such as Hypurin Pork Regular and NPH insulins manufactured by Wockhardt UK Ltd. are still available in Canada. As well, beef insulin can be obtained from Wockhardt UK via Health Canada's Special Access Program.

The best choice of insulin for you is a decision that should be made after a discussion between you and your doctor.

### Possible Health Effects of Insulin

When biological matter such as insulin is introduced into the human body, the body may recognize it as foreign and begin manufacturing antibodies to fight it. In some cases, this process results in a person having to take more insulin to manage his/her diabetes.

In the past few years, a small number of people have reported difficulty managing their diabetes with human biosynthetic insulins. They reported having hypoglycemia without clearly recognizable symptoms, and wide and sudden swings in blood glucose (sugar) levels. The reasons for these difficulties are unclear.

A review of the major clinical studies on insulin showed that the safety and effectiveness of human biosynthetic insulin and those of animal-



sourced insulin are comparable. In addition, the number and types of adverse reactions reported with human and animal insulin were similar, based on the number of patients using each product. In fact, adverse reactions such as hypoglycemia (low blood glucose), may occur while taking either type of insulin.

Hypoglycemia can occur regardless of what type of insulin you take and can cause fatigue, sweating, heart palpitations, disturbed behaviour, hunger, loss of consciousness, or in extreme circumstances even death. It may be brought on:

- When the amount of food you eat is not balanced with the amount of insulin you take (or you have a change in your diet).
- When you have engaged in too much activity and not eaten enough food.
- If the insulin dose taken is more than your body needs at the time (e.g., your insulin needs may change with illness).
- If there is a change in your dosage regime and/or type of insulin or insulin product.

It is important that you understand why low blood glucose occurs, what to do about it, and how to prevent it in the future. Symptoms and signs of hypoglycemia can vary from person to person and can be very subtle and hard to recognize, regardless of the type of insulin you use. Your ability to recognize the symptoms of low blood glucose may also be affected by other medications taken, as some medications may mask the symptoms of hypoglycemia. This means that you might not be aware of your blood glucose being low which could be dangerous.

## Minimizing Your Risk

The more difficult it is for you to manage your blood glucose, the more likely you are to suffer a variety of reactions not only to your disease, but also to your insulin. Take the following steps to help manage your diabetes and to prevent hypoglycemia.

- Consult with your doctor to decide on

the most appropriate insulin treatment for you.

- Ask about and learn to recognize the possible symptoms of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia), and how to manage both effectively.
- Your doctor can help by suggesting strategies to prevent or deal with hypoglycemia. You can also play an active role by ensuring that you monitor your blood glucose regularly.
- Consult a dietician. Eat snacks between meals, at bedtime and especially before you exercise.
- Know your insulin. There are many different insulin products available in Canada and some of them look and sound similar. It is important that you use the insulin advised by your doctor.
- Let your doctor know if you are feeling ill, as your insulin requirements may change during this time.
- Always consult your doctor before taking new medications and notify any treating physician of your diabetes and insulin treatment.
- Wear a medic-alert bracelet.

## Health Canada's Role

Health Canada ensures the safety, quality, and efficacy of insulin available to Canadians and promotes the informed use of these products. Health Canada carries out an extensive pre-market review of information about a product's safety, quality, and effectiveness. A post-market lot release program is an additional check to help assure the product's continued safety for human use.

In addition, Health Canada monitors adverse effects associated with taking insulin. Reporting adverse reactions helps to identify trends and this information is shared with health care professionals and consumers. When appropriate, information collected from people also plays a part in updating product information.

## Need More Info?

To report any adverse reactions with the insulin you are currently taking, call the following toll-free phone or fax lines:  
Tel: 1-866-234-2345  
Fax: 1-866-678-6789

Calls will automatically be routed to the appropriate regional adverse reaction monitoring office.

Adverse reaction reports can also be mailed to the addresses listed below or by visiting the Health Canada Web site at:  
[www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index_e.html)

For a list of regional adverse reaction monitoring offices go to:  
[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/centres/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/centres/index_e.html)

To import insulin authorized in other countries, contact: Health Canada's Special Access Programme (SAP) -  
[www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index_e.html)  
Tel: (613) 941-2108

For more information about diabetes, visit:

Health Canada's Diabetes Web site:  
[www.hc-sc.gc.ca/dc-ma/diabete/index\\_e.html](http://www.hc-sc.gc.ca/dc-ma/diabete/index_e.html)  
Public Health Agency of Canada's Diabetes site:  
[www.phac-aspc.gc.ca/ccdpc-cpcmc/diabete-diabete/index.html](http://www.phac-aspc.gc.ca/ccdpc-cpcmc/diabete-diabete/index.html)

The Canadian Diabetes Association:  
[www.diabetes.ca/](http://www.diabetes.ca/)

Association Diabète Québec:  
[www.diabete.qc.ca/](http://www.diabete.qc.ca/)

For additional articles on health and safety issues go to the It's Your Health Web site at:  
[www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)  
You can also call toll free at 1-866-225-0709  
or TTY at 1-800-267-1245\*