

Obtaining Hypurin Porcine Insulin in Canada through the Special Access Program

A guide for patients and prescribers

Why this guide is needed

[Hypurin Porcine Insulin cartridges](#) and the [MyPen2 device](#) needed to deliver the insulin are both manufactured in the United Kingdom by Wockhardt UK. They are not currently marketed in Canada but can be obtained for individual patients through Health Canada's Special Access Program (SAP).

Until recently, Canadian patients who used Hypurin porcine insulin could purchase it at pharmacies across the country. It came in 10 mL vials and was administered using syringes available in Canada. Wockhardt has discontinued Hypurin in vials but will continue to manufacture Hypurin in 3 mL cartridges and in three different formulations: Neutral (called Regular in Canada); Isophane (or NPH); and 30/70 (30% Neutral + 70% Isophane). Each one of these formulations is available in a package containing five cartridges.

This new format creates an additional complication for Canadian patients. Wockhardt's Hypurin cartridges are designed for use with the company's reusable MyPen2 insulin delivery device. MyPen2 is not licensed for sale in Canada and therefore must also be obtained through Special Access. However, the Wockhardt pen is compatible with needles that are commonly used by other brands, and these can be purchased at your local pharmacy.

Patients who need Hypurin cartridges will consequently require access to two different products through two Health Canada Special Access Programs:

1. Hypurin Porcine Insulin cartridges through the [Special Access Program for drugs](#); and
2. MyPen2 through the [Special Access Program for medical devices](#).

The good news is that these two applications operate on different timelines. Patients using Hypurin on an ongoing basis will require repeat requests for insulin for up to a six-month supply. The MyPen2, on the other hand, has a “shelf life [of] 3 years from date of manufacture,” according to Wockhardt. The Special Access Program has suggested that a new application for the pen will normally be required approximately every three years.

This guide explains the steps involved in obtaining both the insulin cartridges and the device needed to administer it.

1. Who applies to the Special Access Program?

Patients cannot apply directly to SAP.

A health-care professional must submit the request on the patient's behalf. For Hypurin insulin and Wockhardt pens, this will normally be the patient's prescribing physician or a nurse practitioner.

2. Applying for Hypurin Porcine Insulin

The forms that physicians use for requesting insulin cartridges and pens are available from the SAP website. The first page is very straightforward and involves providing basic data such as the physician's name and address, the manufacturer, patient's initials, date of birth, the name of the drug (insulin) or medical device (MyPen2), etc. This section outlines the steps for Hypurin insulin cartridges and Section 4 below addresses applications for MyPen2.

The second page of the form asks three questions:

- 1) The **first question** is only relevant to first time requests. The question asks to provide a concise patient history, including other therapies that have been tried and failed or considered and deemed inappropriate. For diabetes patients such as those seeking access to Wockhardt's products the SAP is looking for a few sentences that outline issues related to what must be a negative experience on other insulin products. This can include things like: "other insulin products do not provide adequate control...", "patient had adverse reactions to other insulin products," "patient has tried all other available insulins without success or sufficient control," "patient suffered life-threatening events on synthetic insulins," etc.
- 2) The **second question** on page 2 of the form is only relevant to repeat patients. This question simply asks the physician to report on the prior use of the drug. This is actually a regulatory requirement, that is, physicians must report on the use of the drug including any adverse events encountered with its use. The SAP is simply looking for a few sentences that describe the success of treatment (or lack thereof). Physicians can complete this section by answering something as simple as: "drug well tolerated, no adverse drug reactions, and patient reports better control of their diabetes".
- 3) The **third question** on page 2 is applicable to new and repeat requests alike. This question asks the physician to provide data respecting the use, safety and efficacy of the drug. This question is required by the regulations so it can't be ignored. The physician can answer the question simply by stating that they have read a copy of the Wockhardt product monograph (PM) or prescribing information. If they wish, they may include a published report or article describing the safety and effectiveness of porcine insulin. In earlier guidance provided by the SAP regarding Wockhardt animal insulin, physicians were advised that stating they had read the Wockhardt product monograph was sufficient.

Although patients can't apply themselves to the SAP, they can make the process considerably easier by providing their prescriber with the necessary forms, Wockhardt product information and other information required to complete the application. The text in this guide provides several links to that information.

Clear and concise information is preferable to a lengthy submission.

3. How much insulin can be requested?

For treatment of a chronic condition, Health Canada may authorize up to a six-month supply of a drug through SAP.

The prescriber should calculate the quantity requested from the patient's usual insulin requirements, allowing sufficient insulin for normal use and [appropriate priming](#) of the MyPen2.

Patients should begin the repeat-request process well before their existing supply is exhausted. Time must be allowed not only for SAP authorization but also for Wockhardt to process the order and for international shipment and customs clearance.

4. A separate application is required for MyPen2 (unfortunately)

Authorization to obtain Hypurin cartridges does not provide authorization to import the MyPen2 required to administer the insulin.

MyPen2 is an unlicensed medical device in Canada. A separate request must therefore be made through Health Canada's **Medical Devices Special Access Program**.

The application should explain that:

- the patient requires Hypurin Porcine Insulin;
- Wockhardt has discontinued Hypurin in vials;
- continuing supplies are provided in Wockhardt 3 mL cartridges;
- the cartridges require a compatible reusable insulin delivery device; and
- MyPen2 is the only device that is compatible with Wockhardt's Hypurin cartridges.

As noted above, Wockhardt describes MyPen2 as a reusable insulin delivery device and states that it has a three-year shelf life from the date of manufacture. The Special Access Program understands that the pens have a three-year expiry, so requests for the pen will normally follow an approximately three-year cycle.

5. Wockhardt also has an administrative role

Health Canada's authorization is only one part of the process. Wockhardt has its own administrative requirements before it will supply Hypurin to a Canadian patient. Here are the documents the company requires:

1. Letter of Authorisation from the Special Access Program.
2. An order form, filled out by the prescribing physician.
3. Page 4 of a Pharmacovigilance Agreement (PVA) signed by the prescribing physician. A PVA is kind of like a letter of understanding between the doctor and Wockhardt that information about adverse side effects will be reported. This is also a requirement of the SAP, so is in line with Canadian guidelines.

Patients and prescribers should ensure that both Health Canada's requirements and Wockhardt's requirements have been completed. A delay after SAP authorization does not necessarily mean that the request is being held up by Health Canada; missing information required by Wockhardt can also delay an order. The contact – for physicians only – at Wockhardt is Maisie Davies (Maisie.Davies@wockhardt.co.uk). If patients have concerns or questions, these should be directed to their physician.

6. Identify a Canadian point of delivery

Before the order is shipped, a Canadian point of delivery must be identified.

A community or hospital pharmacy, or physician's office can all be designated as the point of delivery. The local pharmacy is probably the most convenient location because staff are

available to receive the shipment and insulin can easily be refrigerated promptly after delivery.

Because DHL may require payment when the shipment is delivered, patients should make arrangements with the pharmacy or doctor's office before the shipment arrives. Most pharmacies and offices will not want to pay the charges themselves, so the patient should provide the funds in advance, or agree on how and when they will reimburse the amount. If DHL does not receive payment on delivery, it may not leave the insulin at the delivery point for the patient to pick up.

See Section 7 for what to check before paying any charge.

7. Shipping, Customs and DHL

Wockhardt currently uses DHL to ship its insulin products to Canada. An SAP-authorized shipment must still clear Canadian customs. Customs clearance, however, is not the same thing as customs duty.

A copy of the SAP Letter of Authorization should accompany the shipment. Wockhardt and DHL must also ensure that the customs documentation correctly identifies the product and its tax treatment.

The insulin cartridges and the MyPen2 require different SAP authorizations and different customs/GST coding.

Customs / regulatory item	Hypurin cartridges	MyPen2
Product type	Prescription drug / biological	Medical device
Special Access pathway	Drug SAP	Medical Devices SAP
2026 tariff classification	3004.31.00.00 — medicaments containing insulin	9018.31.00.00
Customs duty	Free	Free
GST treatment	Exempt from GST at import	Exempt from GST at import
GST exemption code	Code 56 — prescription drugs and biologicals	Code 57 — medical and assistive devices
Health Canada documentation	Drug SAP Letter of Authorization	Medical Devices SAP authorization

Courier, brokerage or clearance charges are separate from customs duty, so patients should not assume that an unexpected amount requested by DHL is necessarily customs duty. If DHL requests payment before releasing an SAP shipment, the patient or receiving pharmacy should first ask what the charge represents and whether the shipment has been correctly classified and documented. This is important – in the past, DHL has mistakenly paid a customs charge and then sought reimbursement from the patient. This can happen if the necessary tariff and GST codes are not on the package label.

8. When the shipment arrives

The patient, physician or pharmacist should confirm that:

- the correct Hypurin product and quantity have been supplied;
- the insulin has remained temperature-controlled during shipment;

- the cartridges are undamaged;
- the expiry dates provide a reasonable period for use;
- the MyPen2, if included, is the correct device; and
- copies of the SAP authorization and shipping documentation are retained.

Any apparent shipping damage, temperature-control problem or discrepancy in the order should be reported promptly rather than using the affected insulin.

9. Repeat requests should be simpler

Once a patient has successfully obtained and used Hypurin through SAP, subsequent requests should be considerably simpler than the first application.

The prescriber will still need to submit a repeat request for the insulin, but the SAP does not normally require the patient's entire medical history. The request should briefly report the patient's experience with Hypurin, including its effectiveness, tolerability and any adverse reactions.

Before you start the process, this is information to have ready

For the patient

Your name and contact information for the prescribing doctor or nurse practitioner

Name of the Hypurin insulin being imported, and the dose used

Approximate quantity required for six months

Brief history of problems with other insulin products

Preferred delivery point

Pharmacy/clinic contact information

For the prescriber

Current Health Canada Drug SAP request form

Current Medical Devices SAP application form

Wockhardt Hypurin prescribing/product information

MyPen2 Instructions for Use / product information

Wockhardt manufacturer/contact information

Clinical justification

Quantity of insulin requested

Canadian delivery address and receiving contact

Wockhardt ordering documentation

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Points requiring confirmation/clarification

Current Wockhardt ordering forms and procedures for Canadian SAP patients.

Whether or not DHL can legitimately charge any brokerage/clearance fees on these shipments and, if so, under what circumstances.

Exact documentation and wording Wockhardt should place on the DHL shipment for both the insulin cartridges and MyPen2.

Whether the drug and device can be shipped together and, if so, how both SAP authorizations should be shown on the shipment.

One more important point:

The SAP in the past has reported that “about 20% of all requests we receive each year are returned for clarification or additional information. About 10% are returned because the questions were inadequately answered.” So, it’s important to get it as right as possible the first time. Doctors or NPs will often rely on their patients to help with the SAP forms, so it’s best to treat this as a joint project.

Here are the two SAP forms required:

For insulin: <https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/special-access/drugs/special-access-program-form-a-patient-specific-request-c08-010-1-en.pdf>

For MyPen2: <https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/special-access/medical-devices/application-form-special-access-medical-devices.pdf>