Health Canada Santé Canada

Protected B when completed

Special Access Program
Form B - Future use request patient identity unknown C08.010 (1) and (3)

Section A: Practitioner information

Practitioner's name: (First Last)		
Hospital or clinic name:		
Practitioner's address:		
City:	Province:	Postal code:
Telephone #:	Fax #:	
Email:		
If alternate contact is available complete section below		
Alternate contact name: (First Last)		
Telephone #:	Fax #:	
Email:		

Shipping information - Send drug c/o:

O In-patient hospital pharmacy O Practitioner's office O Nuclear medicine
O Blood bank O Government agency depot O Community Pharmacy

Shipping address:		
City:	Province:	Postal code:
Telephone #:	Fax #:	

Section B: Drug and manufacturer information

Manufacturer (name and location):							
Trade name:							
Other name(s):							
PO#:							
Name of contact person (if applicable):							
Route of administration:	O Oral	O I.V.	O I.M.	O Topical	O S.C.	O Other:	
Dosage form:	O Tab	O Cap	O Liquid	O Powder	O Cream	O Oint.	O Patch	O Other:

Section C: Patient-product tracking information

Part 1: 1st Time future request information

(If this is a **Repeat future request** please proceed to Part 2)

Indication requested:

Canada

Dosage form:
Strength requested:
Quantity requested (specify number of vials/tabs/etc.):
1a) Provide the clinical circumstances under which this drug will be needed on a future use basis.

b) Specific to the clinical circumstances described above, please provide details on conventional therapies that would be tried and failed or ruled out.

c) What specifically about the requested drug (e.g. mechanism of action, drug class, dosage form) makes it the best choice for your patient(s)? Please explain.

☐ I, the practitioner, have verified that the drug & indication that I am requesting is authorized by the European Medicines Agency or the United States Food and Drug Administration

d) Please provide recent and relevant data, references, and/or resources in your possession with respect to the use, safety, and efficacy of the drug. The supporting evidence must be directly relevant to the medical emergency specified, be from credible medical/scientific information sources. For citations, please include author(s), title, journal, volume, issue, date, and page information.

☐ Check if reference(s) is/are attached

Part 2: Repeat future requests only

Indication requested:

Dosage form:

Strength requested:

Quantity requested (specify number of vials/tabs/etc.):

1. Specify the quantity remaining on hand (e.g. # of tabs, vials, bottles etc.)

2. Are you replacing expired stock? ○ Yes ○ No

   If yes, specify the quantity remaining being replaced (e.g. # of tabs, vials, bottles etc.)

What is the format of the patient-product tracking information?

O Table below O Separate document

Please provide a list of patients who received the previous supply in the table below:

Patient initials (first. last e.g. J.S)	Unborn child? (**Y**es **N**o)	Date of Birth (mm/dd/yyyy)	Sex (**M**ale, **F**emale, **O**ther)	Indication for Use of Drug	**N**ew or **R**epeat patient via the SAP for this drug?	Dosage and Duration (e.g. #mg bid x #days)	Quantity	Date of administration -from (mm/dd/yyyy)	Date of administration – to (mm/dd/yyyy)
	O Y O N		O M O F O O		O N O R				
	O Y O N		O M O F O O		O N O R				
	O Y O N		O M O F O O		O N O R				
	O Y O N		O M O F O O		O N O R				
	O Y O N		O M O F O O		O N O R				
	O Y O N		O M O F O O		O N O R				
	O Y O N		O M O F O O		O N O R				
	O Y O N		O M O F O O		O N O R				

Section D: Practitioner attestation & signature	
I, the practitioner, am accessing this non-marketed drug for use in the emergency treatment of patients suffering from a serious or life-threatening condition under my care in accordance with the *Food and Drug Regulations* C.08.010. I, the practitioner, attest that other therapies have been tried and failed or are considered medically inappropriate or are unavailable on the Canadian market at this time. I, the practitioner, am aware that by accessing this drug through the SAP, the sale of the drug is exempt from all aspects of the *Food and Drugs Regulations* including those respecting the safety, efficacy and quality. I, the practitioner, agree to provide a report on the results of the use of the drug including information on adverse drug reactions and, on request, to account for quantities of the drug received. I, the practitioner, attest that the drug supply will be administered to patients and will maintain records of those patients including the indication, quantity released, and the date the drug was administered and will provide them to Health Canada upon request. By signing below, I certify that all information is true and correct to the best of my knowledge.	
Practitioner's Signature:	Practitioner license # or College license #: Date:

Special Access Program, Therapeutic Products Directorate
c/o Health Canada, AL 3105 A, Tunney's Pasture, Ottawa, ON K1A 0K9

Regular business hours are weekdays from 8:30 am to 4:30 pm Eastern Standard Time (EST) **Fax** all requests to **(613) 941-3194**

For after hours and urgent requests requiring immediate attention please follow up with a call to the SAP at: (613) 941-2108

Website: www.healthcanada.gc.ca/sap | **Email:** hc.sapd-pasm.sc@canada.ca

Privacy notice

The personal information you provide to Health Canada is governed in accordance with the *Privacy Act* and is collected pursuant to section C.08.010 (1) of the *Food and Drug Regulations*. The information is used for the purpose of assessing requests for access to drugs under the Sale of New Drug for Emergency Treatment provisions of the *Food and Drug Regulations*.

Pursuant to section C.08.010 (1) of the *Food and Drug Regulations*, the practitioner agrees to report to Health Canada and the manufacturer results of the use of the drug in the medical emergency, including information respecting any adverse reactions encountered. This information is used for the processing of requests and may contribute to the detection of potential product-related safety issues as well as to the benefit-risk assessments of these products.

In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*. This personal information collection is described in *InfoSource*, available online at www.infosource.gc.ca. Refer to Personal Information Bank Special Access Programme - Pharmaceuticals, Biologic and Radio-Pharmaceuticals [HC PPU 414].

In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at 613-946-3179 or privacy-vie.privee@hc-sc.gc.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.