



INSTRUCTIONS ON HOW TO ORDER HYPURIN PORCINE INJECTION

HYPURIN PORCINE is not a registered product but is available on the Special Access Scheme (SAS) on a case by case basis. It is classed as a Category B product.

The following products are available through SAS from Aspen Pharmacare Australia:

Trade Name & Dosage Form	Price / Unit (Excl GST)	GST	Price / Unit (Incl GST)
Hypurin Porcine Neutral 10ml x 1 Vial	\$ 72.00	\$ 7.20	\$ 79.20
Hypurin Porcine Neutral 3ml x 5 Cartridges	\$ 99.00	\$ 9.90	\$ 108.90
Hypurin Porcine Isophane 10ml x 1 Vial	\$ 72.00	\$ 7.20	\$ 79.20
Hypurin Porcine Isophane 3ml x 5 Cartridges	\$ 99.00	\$ 9.90	\$ 108.90

Applications can only be made by registered medical practitioners by filling out the Category B form (see below). TGA approval is required on a patient by patient basis.

Information required by the TGA for applications:

The patient

- Patient details** Initials, Date of birth (or age), Sex, Patient ID or unit record number (if applicable), Diagnosis. Previous approval numbers for that patient, if applicable.
- Clinical justification** An outline of the seriousness of the patient's condition, details of past treatment and, if other approved treatments are available, justification for the use of the unapproved product in preference to those treatments.

The product

- Product details** For unapproved medicines - active ingredient, trade name, dose form, supplier.
For unapproved medical devices - name of device, supplier
- Administration and monitoring regime** Dosage, route of administration, duration of treatment, details of proposed monitoring.
- Efficacy/safety data** Efficacy and safety data sufficient to support the proposed use of the product. A copy of the reference articles from which the data have been obtained should be included.

The prescriber

- Details** Name, postal address, phone number, fax number.

Send applications to:

Phone 02 6232 8111

Fax 02 6232 8112

Postal The Medical Officer, SAS
Drug Safety and Evaluation Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

How long does it take for TGA approval?

Generally, it takes the TGA 2 days to approve the application.

What if my request is urgent?

If your request is urgent, a phone request can be made. Alternatively, the application can be faxed to the TGA. On the bottom of your application please write: 'FAX RESPONSE ASAP'.

NOTE: phone requests should be reserved for cases where there is an urgent medical need for access to the product.

How do I get the product once the TGA has given approval?

Complete the SAS Order Form below and fax or post to Aspen Pharmacare to organise supply. Aspen Pharmacare will require authorisation to release the product. An approval number is issued by the TGA and will appear in the TGA's approval letter sent to the requesting doctor. This number must be quoted in all correspondence with Aspen Pharmacare.

The stocks will be sent to the doctor's office by courier in a cold storage container. The doctor will then in turn notify and supply the patient when the goods are received.

How much does it cost and how do I pay for the stocks?

The prices are in the price list above. The prices include the cost of delivery to the doctor's office. Please send a cheque for the correct amount made out to "Aspen Pharmacare Australia Pty Ltd" when placing the order with Aspen. Alternatively, if the stocks are required urgently, Aspen will ship the goods out first and the doctor can send in the payment later. The doctor will then get reimbursed by the patient.

Further information

Please contact Aspen Pharmacare by phone on **(02) 8436 8300** or fax on **(02) 9901 3540** or visit our website at www.aspenpharma.com.au.

SPECIAL ACCESS
SCHEME
ORDER FORM



Aspen Pharmacare Australia Pty Ltd
ABN: 51 096 236 985
34-36 Chandos Street, St Leonards NSW 2065
Phone: (61 2) 8436 8300 ~ Fax: (61 2) 9901 3540
Email: aspen@aspenpharmacare.com.au
Web: www.aspenpharma.com.au

Patient Initials: _____ Date of Birth: _____ SAS Approval No: _____

Indication: _____ Doctor's Name: _____

Product Name: _____ Packs Required: _____ Total Order Value: _____

Contact Name: _____ Phone No: _____ Fax No: _____

Delivery Address:

Date to deliver by: _____

Business Hours
for Delivery: _____

PLEASE FAX OR POST ORDER FORM WITH APPROVAL LETTER TO ASPEN PHARMACARE

Important:

- Should the patient experience an ADVERSE EVENT whilst receiving this product, please immediately inform Aspen Pharmacare Ph: (02) 8436 8300.
- Whilst all efforts will be made by Aspen Pharmacare to facilitate access by Doctors and their Patients to this product via the S.A.S the Company reserves the right to discontinue supply.