Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 125810 "TBSF" High Purity Factor IX Concentrate

ARTG entry for	Medicine Listed (Export Only)
Sponsor	CSL Behring Australia Pty Ltd
Postal Address	189-209 Camp Road, BROADMEADOWS, VIC, 3047 Australia
ARTG Start Date	1/03/2006
Product category	Medicine
Status	Active
Approval area	Export only Medicines

Conditions

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1. "TBSF" High Purity Factor IX Concentrate

Product Type Composite Pack **Effective date** 1/03/2006

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

"TBSF" High Purity Factor IX Concentrate is indicated for the treatment of haemorrhages, for use in surgery, and as prophylaxis in patients with haemophilia B. "TBSF" High Purity Factor IX Concentrate is not indicated for the treatment of factor II, VII or X deficiencies because it does not contain therapeutic levels of these coagulation factors. "TBSF" High Purity Factor IX Concentrate is not indicated for the treatment of haemophilia A patients with factor VIII inhibitors.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Not recorded	2 Years	Store at 2 to 8 degrees Celsius	Not recorded	Do not Freeze Refrigerate Protect from Light

Pack Size/Poison information

Pack Size	**Poison Schedule**
500 IU	Not scheduled. Not considered by committee

Components

1. Water for Injections - Diluent

Dosage Form	Injection, diluent for
Route of Administration	Intravenous
Visual Identification	Clear, colourless solution free from visible particles

2. "TBSF" High Purity Factor IX Concentrate

Dosage Form	Injection, powder for
Route of Administration	Intravenous
Visual Identification	A white freeze dried powder plug or friable solid

Active Ingredients

Factor IX	**50 IU/mL**

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