MEDICINES ACT 1968

PRODUCT LICENCE No. 3070 / 0004 has been granted under and subject to the provisions of the Medicines Act 1968 to

Speywood Laboratories Ltd
Chancel House
East Street
Bingham
Nottingham NG13 8DR

in respect of the products, particulars of which are set out in Part 1 of the attached Schedule. The Licence is subject to the further provisions set out or referred to in Part 2 of the said Schedule.

This Licence, unless previously suspended, revoked or varied as to the period of its validity, shall continue in force until the end of a period of five years from the date on which it was granted.

Date granted : 27 August 1976

GRO-C

A person authorised to sign on behalf of the Secretary of State for Social Services.

1st March 1977.

Department of Health and Social Security,
Finsbury Square House,
33/37A, Finsbury Square,
London, E.C.2.

MEDICINES ACT 1968

Product Licence No. 3070 / 0004

SCHEDULE

Part 1 - PARTICULARS OF THE PRODUCTS TO WHICH THE LICENCE RELATES

1.	Name of Product:	Koate
2.	Pharmaceutical form:	Lyophilised Powder for Reconstitution with sterile water for injection for intravenous injection
3.	Active constituents:	Antihaemophilic Factor (HUMAN)
4.	Uses:	Treatment of Haemophilia A
5.	Recommended dose and dosage schedule:	10 to 20 units per Kg individualized according to the needs of the patient.
6.	Contra-indications, Precautions and Warnings:	1. Antihemophilic Factor (Human), Koate™, is intended for treatment of bleeding disorders arising from a deficiency in Factor VIII. This deficiency should be proven prior to administering Koate™ since no benefit may be expected from its use in treating other causes of hemorrhage. 2. Antihemophilic Factor (Human), Koate™, should be kept at a temperature below 8°C (46°F) until reconstituted for use. After reconstitution, administer promptly (within 3 hours). Do not refrigerate after reconstitution. NOTE: The recommendation to administer promptly after reconstitution is intended to avoid the ill effect of any possible bacterial contamination occurring during reconstitution. Koate™ is fully stable, without potency loss for at least 24 hours at room temperature after reconstitution. 3. Administer only by the intravenous route. 4. A filter should be used prior to administering the reconstituted Koate™ solution. This may be accomplished using the enclosed sterile filter needle. See Reconstitution and Administration directions.

continued

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continued Product Licence No.3070/0004

SCHEDULE
Part 1 - PARTICULARS OF THE PRODUCTS TO WHICH THE LICENCE RELATES

5. Koate™ contains measurable levels of blood group isoagglutinins which are not clinically significant when controlling relatively minor bleeding episodes. When large or frequently repeated doses are required in patients of blood groups A, B, or AB, the possibility of intravascular hemolysis should be considered.

6. Administration equipment and any reconstituted Koate™ not used should be discarded.

7. Koate™ concentrate is a purified dried fraction of pooled plasma obtained from many donors. SINCE THE PRESENCE OR ABSENCE OF HEPATITIS VIRUS IN KOATE™ CONCENTRATE CANNOT BE PROVEN WITH ABSOLUTE CERTAINTY, THE PRESENCE OF SUCH A VIRUS SHOULD BE ASSUMED and the hazard of administering Koate™ concentrate should be weighed against the medical consequences of withholding it.

7.	Method of retail sale or supply:	Through Haemophilia Centres and Hospitals.
8.	Manufacturer of dosage form:	Cutter Laboratories Inc Fourth and Parker St San Francisco California CA 94710

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SCHEDULE

Part 2 - FURTHER PROVISIONS SUBJECT TO WHICH THE LICENCE HAS BEEN GRANTED

1. All the provisions of Part I of Schedule 1 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (SI 1971 No 972) as amended by the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1972 (SI 1972 No 1226) and the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1974 (SI.1974 No 1523) shall apply.

2. The number of the Licence shall appear on all containers or packages in which the product(~~s~~) is/~~are~~ packed, on any package inserts or accompanying literature and on any data sheets issued in connection with the product(~~s~~).

3. The product(~~s~~) shall not be recommended to be used for any purposes other than those specified in Part 1 of this Schedule as Uses.

4. The specification of the constituent and of the finished product shall be in accordance with the information contained in the application for this product licence.

5. The product shall be manufactured only in accordance with the method given in the application for this product licence.

6. The licence holder shall on request furnish to the licensing authority from every batch of the product, or from such batch or batches as the licensing authority may from time to time specify, a sample of such amount as the authority may consider adequate for any examination required to be made; and the licence holder shall, if required by the licensing authority, furnish full protocols of the tests which have been applied.

7. If the licensing authority so direct, the licence holder shall not sell or supply any batch in respect of which a sample is or protocols are furnished under paragraph 6 until a certificate authorising the sale or supply of the batch has been issued to him by the licensing authority.

8. The licence holder shall, on being informed by the licensing authority that any batch of the product has been found by the licensing authority not to conform as regards strength, quality and purity with the relative requirements, and on being directed so to do, withdraw the remainder of that batch from sale and supply and, so far as may be practicable, recall all issues already made from that batch.