H02AB09SOR075X0 / Hydrocortisone Oral Solid 10 mg

1. DESCRIPTION OF THE MEDICINE

1.1 DCI:	Hydrocortisone
1.2 Synonym:	
1.3 Pharmaceutical form:	Oral solid
1.4 Concentration:	10 mg
1.5 Commercial presentation:	Box of blister/string/personal dose bottle, not hospital packaging.
1.6 Routes of administration:	Oral route
1.7 Useful life:	In accordance with current legal regulations
1.8 Storage conditions: - Not exceeding 30°C	- The primary packaging must guarantee its physical-chemical stability and microbiological.

2. PACKAGING

2.1 Primary packaging:

2.1.1 Features:	The information must be printed with clear characters in Spanish. or English clearly legible and indelible in normal handling.
2.1.2 Labeling:	It must be printed at least: international common name, form pharmaceutical, concentration, route of administration, batch, expiration date.

2.2 Secondary packaging:

2.2.1 Features:	Cardboard box or other material that protects the medicine from the handling to which it will be subjected during storage. The size must be consistent with the internal content
2.2.2 Labeling:	It must contain at least the following information: common name international, pharmaceutical form, concentration, route of administration, batch and Expiration date; printed in English or Spanish, with characters clear, clearly legible, allowing for quick reading and being resistant to handling. Preferably include the legend: "Free medicine."

3.3 Tertiary packaging:

2.3.1 Features:	Cardboard boxes or other stowage-resistant material, in good condition, sealed with packing tape, its size must be consistent with the internal content in order to ensure the integrity of the product during transport and storage. The box must have the necessary symbols for correct handling, preservation and stacking during storage.
2.3.2 Labeling:	It should preferably be labeled in Spanish/English with legible letters,

clearly identifying the balances; and, on adhesive labels, include at least the following information:

- Generic name / INN
- Pharmaceutical form
- Concentration of the active ingredient
- Package contents
- Batch number
- Expiration date
- Manufacturer/supplier and country of origin
- Storage conditions

3. SPECIAL CONSIDERATIONS

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4. HEALTH AND TECHNICAL RECEPTION REQUIREMENTS (Post-registration control level I)

SANITARY REGISTRATION OF THE COUNTRY OF ORIGIN OR ITS EQUIVALENT AND GOOD MANUFACTURING PRACTICES (GMP); OR, WHO-TYPE PHARMACEUTICAL PRODUCT CERTIFICATE. IMPORT AUTHORIZATION ISSUED BY THE NATIONAL AGENCY FOR SANITARY REGULATION, CONTROL, AND SURVEILLANCE (ARCSA), IN ACCORDANCE WITH THE EXCEPTIONS ESTABLISHED IN CURRENT LEGAL REGULATIONS.

SUBMIT FOR TECHNICAL RECEPTION:

- Copy of the Health Registration Certificate from the country of origin or its equivalent and a Certificate of Good Manufacturing Practices; or, a WHO-type Pharmaceutical Product Certificate; - A simple copy of the Quality Control Analysis Certificate for

the batch(es) of the medication to be delivered; - A simple copy of the purchase order/acquisition contract (depending on the

procurement process applied), in order to verify the technical specifications of the contracted object.

- Simple copy of the import authorization issued by ARCSA.

5. PERSONS RESPONSIBLE AND DATE

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National Directorate for the Regulation of Medicines and Medical Devices