

PRODUCT SPECIFICATION


DC 16

Edic.: 02



PRODUCT:	DURAGEN Register number: 01144 – H
REVISION (yymmdd):	180530

GENERAL CHARACTERISTICS:

DESCRIPTION	<p>Extender for boar semen in vitro at 15-17°C, for an approximate period of 10 – 12 days depending on sperm quality that maintains its physico-chemical parameters (pH, pka, osmolality) as well as its spermatoc functional functionality.</p> <p>Product for Swine Artificial Insemination use.</p>
PRESENTATION	 <p>The image shows the packaging for Magapor DURAGEN. It features a blue and orange design with the Magapor logo at the top right. A circular seal on the left says "HIGH PERFORMANCE". The word "DURAGEN" is written in large, bold, red letters with a black outline. Below it, a red box contains the text "Diluyente de extra larga duración para semen de verraco" and "Extra long-term boar semen extender" in white.</p>
PRODUCT PREPARATION FOR A CORRECT USE:	<p>Dilute the content of the package at a proportion of 42,305 grams/litre of bi-distilled or distilled water or, if failing, laboratory water of type II at a temperature of 37C°, stirring the solution to obtain a better result. Once the extender is reconstituted, mix with the ejaculate, trying that temperature differences between them be as close as possible.</p>

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**PHYSICOCHEMICAL PARAMETERS OF THE EXTENDER RECONSTITUTED**

pH	Conductivity (mS/cm)	Osmolality	Grados BRIX
6,90-7,50	8,5-11	290-320	3,8-4,5

SPECIFICATIONS:

PHARMACEUTICAL PRESENTATION FORM:	
	<p>Physical form: odourless white powder.</p> <p>Characteristics of the packaging: heat-sealed aluminium complex in formats for 1 Litre, 5 Litres and 100 Litres of extender.</p> <p>Sealing system: heat-sealing.</p>

QUALITATIVE COMPOSITION:	
	<p>Glucose.</p> <p>Sodium bicarbonate.</p> <p>Stabilizers of the spermatozoon plasmatic membrane.</p> <p>Excipients.</p> <p>It contains antibiotics complying with the European Directive 90/429/EEC.</p>

MANUFACTURING METHOD:	
	<p>MAGAPOR DURAGEN extender is manufactured with chemical products of pharmaceutical quality or, if failing, of food quality.</p> <p>There is no thermic process during the elaboration process, for a chemical synthesis of pure raw materials from the chemical or food industry is used, so there is no possibility of transmitting infectious agents. This product does not contain any protein of animal origin and thus is free of B.S.A. (bovine seroalbumin), preventing the transmission of potential pathogens.</p>

OTHERS:	
METHOD OF ADMINISTRATION:	Not applicable (Do not inject. Do not ingest).
MAXIMUM PRESERVATION FOR USE AFTER RECONSTITUTION:	2-3 days - Store in a chamber between 2°C y 8°C, always checking that the product is hermetically sealed, protected from air and external agents.

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POSSIBLE COLATERAL EFFECTS (LOCAL AND/OR GENERAL, INCOMPATIBILITIES AND PHARMACOLOGICAL ANTAGONISMS):	None.
INTOXICATION MAND OVERDOSE IN ANIMALS:	Not applicable.
INTOXICATION IN HUMAN BEINGS:	Not applicable (Do not ingest. Keep the product out of the reach of children).
UNDESIREED BIOLOGICAL EFFECTS:	Not applicable.
CONTROL OVER RESIDUES OF MEDICINAL PRODUCTS:	Not applicable.
CORRECT PRESERVATION OF THE PRODUCT:	Store in a cool and dry place, away from direct sunlight and moisture.

EXPIRY DATE (VALIDITY PERIOD):	
	24 MONTHS from manufacturing date (see package).

HOW TO DILUTE THE EXTENDER

1. Heat up 1 liters of distilled water till 37°C degrees on an Erlenmeyer flask
2. Once heated, place it on a magnetic stirrer with a magnet



3. Add the full content of the 1L package into the 1L of heated distilled water and mix during 15-20 minutes.
4. Once completely diluted, the extender is ready to use.

DURAGEN, EXTRA LONG-TERM EXTENDER. WHY DURAGEN IS DIFFERENT.

DURAGEN is an extra long-term extender, which causes the spz take more time to activate when we warm the sample to evaluate the motility (minimum 15 minutes and up to 30 minutes). That means that the spz need more time to get activated when you warm a seminal dose, but this does not happen into the reproductive tract of the sow, since there's a direct interaction between DURAGEN and the spz (it's not only an influence of the temperature), that will generate biochemical changes that will make the spz able for fertilization. DURAGEN keep the spz in an optimal state and their activation is due to the reproductive tract of the sow.

Motility assessment protocol

- Sperm motility will be evaluated with a phase contrast microscope and slide at 37°C.
- Warm up the semen sample 15 minutes at 37°C before the analysis.
- Examine the motility of the sample, placing a drop of semen sample in a tempered slide (37 ° C) with a tempered coverslide.
- Evaluate at least five different fields of each drop and calculate the average.
- If we see that motility is not adequate, leave the sample warming and check it every 5 minutes till 30 minutes of sample incubation for the correct activation of the spermatozoa (similar to what would happen in the female reproductive tract)