



# PHOVIA

## Topical photoconverter gel

To be used with Phovia LED Lamp for delivery of Fluorescent Light Energy

## Instructions For Use



For animal use only

### 1. Device Description

The PHOVIA System is composed of two products: the PHOVIA LED Lamp, and the PHOVIA Gel which is a physical barrier product for topical application to animals. The PHOVIA Gel is a topical gel containing chromophores. It is used with the PHOVIA LED Lamp that delivers non-coherent blue light. When PHOVIA Gel is illuminated by the PHOVIA LED Lamp as per instructions, it emits Fluorescent Light Energy. The PHOVIA Gel is presented in two containers, a jar and an ampule. The contents of both containers must be mixed together, in the jar, just before application.

Please read this document in conjunction with the PHOVIA LED Lamp instructions for use.

### 2. Instruction for Use

The PHOVIA System is intended to create an environment supporting the skin's own regeneration mechanisms in a physical way.

### 3. Warnings

Do not use if the animal:

- a) has photosensitivity due to a condition or is taking medicines / products known to induce photosensitivity reactions;
- b) has known skin hypersensitivity;
- c) has known porphyria condition.

### 4. Precautions

- This product has not been tested in pregnant or lactating animals. The veterinary surgeon should apply a risk-benefit judgment when considering using the product.
- Before using the PHOVIA Gel, it is important to read and understand the instructions for use, warnings, precautions, potential complications/adverse reactions and the use of the PHOVIA System.
- There are no serviceable parts in the PHOVIA Gel. Do not use if the product appears damaged, if jar gel is not translucent, or if ampule gel is colourless.
- The gels are light sensitive. Keep unused ampules inside the protective foil pouch and keep the pouch and the jars in the original box and protected from light.
- The PHOVIA Gel should be kept away from open flames and excessive heat. The PHOVIA Gel should be kept between 2°C and 25°C.

Excursions down to -20°C or up to 30°C are allowed for a maximum of 48 hours.

- Each PHOVIA Gel application (1 jar and 1 ampule) is a single use product. Do not use more than once.
- Avoid looking at the PHOVIA LED Lamp without eye protection when in use. Suitable blue-filtering safety goggles (supplied with lamp) must be worn by anyone in the room that might be exposed to the light (such as the veterinary surgeon, the assistant or the animal owner) during illumination. The animal's head should be facing away from the lamp or the animal's eyes should be covered to avoid the animal looking directly at the lamp when in use.
- Signs of local infection should be treated as per local veterinary clinic or veterinary hospital practice protocol.
- The PHOVIA System should be used by a trained veterinary surgeon or, in accordance with current legislation, a suitably trained person under the veterinary surgeon's supervision.

### 5. Potential Complications

Fluorescence Light Energy is generally safe but like with any other use, it might sometimes cause adverse events. Adverse events that can be associated with Fluorescence Light Energy in general are agitation, burning, dry/itchy skin, erythema, hyperactivity, irritability, oedema or worsening of skin diseases.

Potential complications and adverse events associated with the PHOVIA System are: hair color change, erythema that regresses within 6-12 hours, skin hyperpigmentation, pain and burning sensation at the wound site and fatigue.

### 6. Product Specifications

Each PHOVIA Gel application is for single use only and is supplied as a jar (20 g) containing the clear carrier gel and an ampule (2.0 g) containing the orange colored chromophore gel which should be mixed together (see section 7. Directions for use). This PHOVIA Kit box contains materials for five (5) PHOVIA Gel applications.

## 7. Directions for Use

Always use in conjunction with the PHOVIA LED Lamp instructions for use. Mixing Instructions and PHOVIA Gel application procedure: PHOVIA Gel should be prepared and applied in a clean area.

1. Remove the contents from the PHOVIA Gel box: 1 ampule, 1 jar and 1 mixing spatula. Place the remaining ampules back inside the foil pouch and the pouch inside the box, protected from light.
2. Put gloves on.
3. Remove the lid from the jar and the tip of the ampule.
4. Transfer the contents of the ampule into the jar.
5. Use the supplied spatula to stir the mix well until orange colour is uniform.
6. Cover the jar until time of application.
7. Remove any dressings the animal may already have.
8. Gently clip any hair that prevents full contact of the PHOVIA Gel with the surface of the skin.
9. Clean the skin with sterile saline solution if needed. Should a different solution or product be used for cleaning the skin, please ensure that you rinse the skin with sterile saline solution after.
10. Prepare the PHOVIA LED Lamp, as per its instructions for use.
11. Ensure the animal is in a comfortable position, with the skin accessible for the procedure and the animal's head facing away from the light (or cover the animal's eyes to protect from the light).
12. Use the spatula to apply approximately a 2 mm thick layer of the PHOVIA Gel on the surface of the skin.
13. Ensure everyone in the room (such as the veterinary surgeon, the assistant or the animal owner) wears the supplied safety goggles before turning on the PHOVIA LED Lamp. Two sets of goggles are provided with the PHOVIA LED Lamp. Clean the goggles in between uses, as indicated in the manufacturer instructions.
14. Follow PHOVIA LED Lamp instructions for use. The distance between the light source and the skin area is achieved by positioning the lamp's cone as close as possible to the skin (without touching the surface of the skin). The LED's are 5 cm from the edge of the cone. Ensure that the distance is maintained throughout the illumination.
15. Begin the 2-minute illumination period.
16. The lamp will shut down automatically once the 2-minute period is completed. The animal should not be left unsupervised.
17. Once the procedure is completed, gently remove the PHOVIA Gel from the skin with a gauze soaked in sterile saline solution.
18. Dispose of all materials after use following veterinary clinic or veterinary hospital disposal procedures.

19. The 2-minute illumination should be repeated twice weekly until the skin is regenerated. Alternatively, two consecutive 2-minute applications (apply the gel, illuminate, remove gel, rest 1 minute, re-apply the gel, illuminate and remove gel) should be repeated weekly until the skin is regenerated.

## 8. Glossary of Symbols

SYMBOL	DESCRIPTION
	Lot number (Batch)
	Expiration date
	Storage – Temperature
	Single Use
	Protect from heat sources

## 9. Technical Support

For technical support, please address your questions to your local Vetoquinol representative.

## 10. Disposal of the product

Waste materials and any unused Phovia Gel should be disposed of in accordance with local requirements.

## Distributors

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