

Topical Chromophore Gel



For use in dogs and cats only

Instructions for use

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

BOX CONTAINS:

Carrier Gel, 20 g each

Chromophore Gel. 2 g each



DEVICE DESCRIPTION

The PHOVIA system reduces healing time by up to 50% compared to traditional methods. The PHOVIA System consists of two components: the PHOVIA LED Lamp, and the PHOVIA Gel. 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 carrier gel iar and a chromophore gel ampule. The contents of both containers must be mixed together just before application.

WARNINGS

Do not use if the animal:

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

PRECAUTIONS

- Both gels are light sensitive. Keep unused ampules inside the protective foil pouch and keep jars and ampules inside the original box to protect from light.
- This product has not been tested in pregnant or lactating animals.
- 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.
- Do not use if the product appears damaged, if iar gel is not translucent, or if ampule gel is colorless.
- The PHOVIA Gel should be kept away from open flames and excessive heat. The PHOVIA Gel should be kept between 35.6°F and 77°F. Excursions down to 29°F or up to 86°F are allowed for a maximum of 48 hours.

- Each PHOVIA Gel application (1 carrier gel and 1 chromophore ampule) is a single use product. Do not use the mixed contents for more than one application.
- 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 veterinarian, technician, assistant or pet owner) during illumination. The animal's head should be facing away from the lamp or the animal's eyes should be covered to avoid looking directly at the lamp when in use.
- Signs of local infection should be treated as per local veterinary hospital protocol.
- The PHOVIA System should be used by a trained veterinarian, technician or other suitably trained person in accordance with all applicable laws and regulations.

POTENTIAL COMPLICATIONS

Florescence Light Energy is generally safe but, like with any other device, adverse events may occur. Adverse events that can be associated with Fluorescence Light Energy in general are agitation, burning, dry/itchy skin, erythema, hyperactivity, irritability, edema 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.

PRODUCT SPECIFICATIONS

Each PHOVIA Topical Gel application is supplied as a jar (20 g) containing the clear carrier gel and a orange chromophore gel ampule (2.0 g), which should be mixed together. This box contains materials for five (5) PHOVIA applications.

3

DIRECTIONS FOR USE

Always use the PHOVIA Gel with the PHOVIA LED Lamp in accordance with the manufacturer instructions. PHOVIA Gel should be prepared and applied to a clean area.

Mixing Instructions and PHOVIA Gel application procedure:

Step 1 - Product Preparation

#1 Remove the contents from the PHOVIA Gel box:



- 1 jar
- 1 ampule
- 1 mixing spatula
- #2 Place the remaining ampules back inside the foil pouch, and place the pouch inside the box to protect it from light.



- #3 Put gloves on.
- #4 Remove the lid from the jar and tip of the ampule.
- #5 Transfer the contents of the ampule into the jar.



- #6 Use the supplied spatula to stir and mix well until the gel is a uniform orange color.
- #7 Cover the jar until time of application.
- #8 Prepare the PHOVIA LED Lamp, as per its instructions for use

Step 2 - Pet Preparation

- #1 Remove any dressings the animal may have.
- #2 Gently clip any hair that prevents full contact of the PHOVIA Gel with the surface of the skin.



#3 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. #4 Ensure the animal is in a comfortable position, with the skin accessible for the procedure and the animal's head covered or facing away from the light.

Step 3 - Application



#1 Use the spatula to apply approximately a 2 mm thick layer of the PHOVIA Gel on the surface of the skin.



 a) Ensure everyone in the room wears the supplied safety goggles before turning on the PHOVIA LED Lamp.



b) Follow PHOVIA LED Lamp instructions for use.



- #2 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 this distance is maintained throughout the illumination.
- #3 Begin the 2-minute illumination period.
- #4 The lamp will shut down automatically once the 2-minute period is completed. The animal should not be left unsupervised.

Step 4 - Cleaning



- #1 Once the procedure is complete, gently remove the PHOVIA Gel from the skin with gauze soaked in sterile saline solution.
- #2 Dispose of all materials after use following veterinary hospital disposal procedures.
- #3 Clean the goggles in between users as indicated in the Phovia LED Lamp instructions.

Step 5 - For Best Results

Apply two applications a week for best results. The illumination process should be repeated weekly until the condition is resolved.

Once a week application:

Two consecutive 2-minute applications: (apply the gel, illuminate, remove gel, rest 1 minute, re-apply the gel, illuminate and remove gel)

Twice a week application:

Perform the 2-minute illumination on two seperate days.

SUPPORT

For customer service call 1-800-267-5707.

This product may be covered by one or more patents or pending patent applications. See https://www.vetoquinol.com/phovia/ip for details and patent status.

DISPOSAL OF THE PRODUCT

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

Manufactured for Vetoquinol USA, Inc. Ft. Worth, TX (USA) 76137 1 (800) 267-5707 www.vetoquinolusa.com



461433 1

4 5