

ZITHRANOL- anthralin shampoo
Elorac Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Zithranol Shampoo
anthralin 1% | microcristalline-encapsulated system

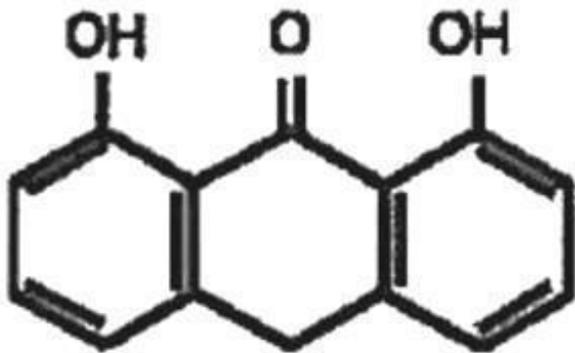
Package Insert:

Rx Only

FOR DERMATOLOGIC USE ONLY
NOT FOR OPHTHALMIC USE

DESCRIPTION

Zithranol Shampoo contains 1% anthralin in a shampoo base containing glyceryl monolaurate, glyceryl monomyristate, citric acid, sodium hydroxide, FD&C Blue No. 1, Macare® G-2C, and purified water. The chemical name of anthralin is 1,8-dihydroxy-9-anthrone and its structural formula is:



CLINICAL PHARMACOLOGY

Zithranol Shampoo contains anthralin, a synthetic compound whose precise mechanism of antipsoriatic action is not yet fully understood. However, numerous studies have demonstrated antiproliferative and anti-inflammatory effects of anthralin on psoriatic and normal skin. The antiproliferative effects of anthralin appear to result from both an inhibition of DNA synthesis as well as from its strong reducing properties. Recently, anthralin's effectiveness as an antipsoriatic agent has also been in part attributed to its ability to induce lipid peroxidation and reduce levels of endothelial adhesion molecules, which are markedly elevated in psoriatic patients. Unlike retinoids and PUVA, anthralin does not inhibit liver microsomal enzyme activity; consequently, the likelihood of adverse drug interactions is greatly reduced when other agents are administered concomitantly with anthralin.

INDICATIONS AND USAGE

Zithranol Shampoo for the treatment of scalp psoriasis in subjects 12 years of age and older (see PRECAUTIONS). Patients should be instructed to use Zithranol Shampoo for the minimum time period necessary to achieve the desired results.

CONTRAINDICATIONS

Use of Zithranol Shampoo is contraindicated in patients who are hypersensitive to anthralin or to any ingredient in this preparation.

WARNINGS

Avoid contact with the eyes or mucous membranes. Discontinue use if a sensitivity reaction occurs or if excessive irritation develops.

PRECAUTIONS

General: For external use only. Contact with fabrics, plastics and other materials may cause staining and should be avoided. Always wash hands thoroughly after use. Keep container tightly capped when not in use. Avoid excessive heat. Keep out of the reach of children.

Carcinogenesis, mutagenesis, impairment of fertility: Although long-term studies in animals have not been performed to evaluate the carcinogenic potential of the drug, there have been no reports to suggest carcinogenic effects in humans after many years of clinical use.

Pregnancy:

Teratogenic Effects: Pregnancy Category C

Animal reproduction studies have not been conducted with Zithranol Shampoo. It is also not known whether Zithranol Shampoo can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Zithranol Shampoo should be given to a pregnant woman only if clearly needed.

Nursing mothers: Because many drugs are excreted in human milk, caution should be exercised when Zithranol Shampoo is administered to a nursing woman.

Pediatric use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Very few instances of contact allergic reactions to anthralin have been reported. Transient primary irritation and staining of hair or skin may occur. The temporary discoloration of hair and skin may be minimized by careful application. Staining of fabrics may be permanent so contact should be avoided.

DOSAGE AND ADMINISTRATION

Zithranol Shampoo should be applied onto wet scalp 3 to 4 times per week (or as directed by the physician). Lather and leave on scalp for 3 to 5 minutes and then rinse thoroughly. Avoid contact with eyes. Although no additional shampoo is necessary to cleanse the hair, a non-medicated shampoo or conditioner can be applied following the use of Zithranol Shampoo, if desired. If no improvement is seen after 4 weeks of treatment, consult the physician.

HOW SUPPLIED

Zithranol Shampoo (anthralin 1%) microcrystalline-encapsulated system is supplied in tubes.

85g NDC 42783-111-85

7.5g NDC 42783-111-07

(physician sample size)

Store at controlled room temperature 68°F to 77°F (20°C to 25°C).

Manufactured for:

Elorac, Inc.

Vernon Hills, IL 60061

U.S. Patent Pending

Caution: Federal law prohibits dispensing without prescription.

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Rev. 01 (10/2011)

TUBE AND CARTON PHOTO:



Zithranol Shampoo
anthralin 1% | microcrystalline encapsulated system

85g Carton Label:

NDC 42783-111-85

Zithranol Shampoo
anthralin 1% | microcrystalline-encapsulated system
85g

FOR DERMATOLOGIC USE ONLY
NOT FOR OPHTHALMIC USE

Rx only



Zithranol Shampoo
anthralin 1% | microcrystalline encapsulated system

85g Container Label:

NDC 42783-111-85

Zithranol Shampoo
anthralin 1% | microcrystalline-encapsulated system

85g

FOR DERMATOLOGIC USE ONLY
NOT FOR OPHTHALMIC USE

Rx only

85g

NDC 42783-111-85

 **ZITHRANOL™ Shampoo**
anthralin 1.0% | microcrystalline-encapsulated system

Rx only

FOR DERMATOLOGICAL USE ONLY

NOT FOR OPHTHALMIC USE

Each g contains:

1% microcrystalline-encapsulated anthralin in a green aqueous shampoo base containing glyceryl monolaurate, glyceryl monomyristate, citric acid, sodium hydroxide, FD&C Blue #1, Macare® G-2C and purified water.

KEEP OUT OF THE REACH OF CHILDREN

See crimp for expiration date and Lot no.

Manufactured for Elorac, Inc.

Vernon Hills, IL 60061. U.S. Patent Pending
Zithranol is a trademark of Elorac, Inc.

Directions for Use:

- 1) Invert cap to puncture seal in neck of tube.
- 2) Wet hair thoroughly.
- 3) Squeeze into palm of hand.
- 4) Lather and leave on scalp for 3 to 5 minutes.
- 5) Rinse with luke-warm water, thoroughly removing the shampoo.

Avoid contact with eyes. Although no additional shampoo is necessary to cleanse the hair, a non-medicated shampoo or conditioner can be used following Zithranol, if desired. Repeat treatment on alternate days as needed or as directed by physician.

Product Storage:

Avoid exposing tube to excessive heat.

Store at controlled room temperature, 73°-80°F (23°-27°C).

Keep container tightly closed, and protect from light.

 **elorac INC.**

Zithranol Shampoo
anthralin 1% | microcrystalline-encapsulated system

7.5g Physician Sample Container Label:

NDC 42783-111-07

Zithranol Shampoo

anthralin 1% | microcrystalline-encapsulated system

7.5g

FOR DERMATOLOGIC USE ONLY

NOT FOR OPHTHALMIC USE

Rx only

**FOR DERMATOLOGICAL
USE ONLY**
**KEEP OUT OF THE
REACH OF CHILDREN**

Manufactured for
Elorac, Inc.
Vernon Hills, IL 60061.
U.S. Patent Pending

DIRECTIONS: Invert cap to puncture
seal. Lather and leave on wet scalp
3-5 minutes. Rinse thoroughly with
lukewarm water. Avoid contact
with eyes.

PRODUCT STORAGE: Avoid exposing
tube to excessive heat. Store between
73°-80°F (23°-27°C). Keep container
tightly closed, and protect from light.

7.5g

Sample – Not for Sale

NDC 42783-111-07

Rx only

 **ZITHRANOL™ Shampoo**
anthralin 1.0% | microcrystalline-encapsulated system

ZITHRANOL

anthralin shampoo

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42783-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Anthralin (UNII: U8CJK0JH5M) (Anthralin - UNII:U8CJK0JH5M)	Anthralin	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCERYL MYRISTATE (UNII: 6992Y81827)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:42783-111-85	12 in 1 CASE		
1		1 in 1 CARTON		
1		85 g in 1 TUBE		
2	NDC:42783-111-07	24 in 1 CASE		
2		1 in 1 CARTON		
2		7.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/05/2012	

Labeler - Elorac Inc. (832590009)

Registrant - Elorac, Inc. (832590009)

Revised: 10/2014

Elorac Inc.