ECZEMOL- potassium bromide, nickel sulfate, and sulfur tablet
PLYMOUTH HEALTHCARE PRODUCTS LLC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

ECZEMOL ®

CAUTION

Federal law prohibits dispensing without a prescription.

DESCRIPTION

ECZEMOL ® is a biochemical homeopathic medication indicated for the **treatment of eczema.**[27,29] The active ingredients in each ECZEMOL ® tablet consist of the following: Potassium Bromide (Kali Bromatum) 1X, Sulphur 1X, and Nickel Sulphate (Niccolum Sulphuricum) 1X. These drug ingredients are listed in the Homoeopathic Pharmacopoeia of the United States (HPUS). [1]

Inactive ingredients: Lactose, Fumaric Acid, and Magnesium Stearate.

Pharmacological class: Homeopathic drug.

Dosage form: Oral 300 mg scored tablet. May be swallowed whole, chewed or dissolved in the mouth and swallowed.

CLINICAL PHARMACOLOGY

The active ingredients in ECZEMOL ® are simple biochemical compounds. The exact mechanism of action is unknown; however, it is believed ECZEMOL ® addresses a primary genetic biochemical defect.

POTASSIUM BROMIDE dissolves and dissociates in the digestive tract into its ionic constituents. Each tablet contains approximately 15 mg of bromide (calculated). Ionic bromide is rapidly and completely absorbed from the intestine and distributed almost exclusively in the extracellular fluids. [7,8] Bromide is eliminated by the kidneys and the elimination half-life is 11-12 days. "Once a day" dosing will lead to a steady state concentration in about seven weeks. [7]

SULPHUR is a naturally occurring mineral that is an essential part of the human body. It exhibits anti-bacterial, anti-parasitic, fungicidal, and keratolytic properties. [26] Each tablet contains approximately 1.5 mg of sulphur (calculated). Sulphur is highly water soluble and as a result is easily excreted by the body via sweat and urine. [22] Since the sulphur found in ECZEMOL ® is a naturally occurring mineral, it is radically different from sulfa drugs (sulfonamide antibiotics). Therefore, **patients who are allergic to sulfa drugs CAN safely take ECZEMOL ®**.

NICKEL SULPHATE dissolves and dissociates in the digestive tract into its ionic constituents. Each tablet contains approximately 0.5 mg of ionic nickel (calculated).

constituents. Each tablet contains approximately 0.5 mg of ionic nickel (calculated). According to studies, 15% to 50% of ionic nickel is absorbed on a fasted stomach. [2] Food markedly decreases the rate and extent of nickel absorption. [3,4] Clinical studies show that serum concentrations of nickel are variable among patients after administering the same dosage. [5] Peak serum nickel concentration is reached about two hours after oral administration. "Once a day" dosing leads to steady state serum concentrations in approximately one week. Nickel is in its highly stable divalent cation state and is therefore not expected to be metabolized to any significant degree in the body. Absorbed nickel is primarily excreted in the urine and elimination half-life is about 21 hours. [3,5] Renal clearance is rapid and efficient, and nickel does not accumulate in the body. [6]

CLINICAL STUDIES

A variety of controlled clinical studies have been performed using various sources of both nickel and bromide in over 300 subjects. Clinical efficacy and safety have been documented in a significant number of subjects. Published and unpublished reports are available upon request. [9,20,21]

INDICATIONS

ECZEMOL ® is indicated for the treatment of moderate to severe eczema and atopic dermatitis. It has been found to work well with a variety of combination therapies.

CONTRAINDICATIONS

Although there are no known contraindications, patients who are allergic to any ECZEMOL ® ingredient should consult a physician prior to taking the medication. (Refer to Section on Hypersensitivity)

WARNING

Do not use if imprinted seal under bottle cap is missing or broken. Do not use if pregnant or nursing. If allergic to nickel or metal objects such as jewelry or if there is a history of blistering hand eczema, see PRECAUTIONS for hypersensitivity information. Lactose intolerant patients may have gastrointestinal difficulty. This has very rarely been reported at the doses used.

PRECAUTIONS

Carefully adjust dosage to weight when treating young children. Use cautiously in setting of kidney disease. (see Dosage and Administration) If skin rash appears or if nervous symptoms persist, recur frequently, or are unusual, discontinue use.

Hypersensitivity

Caution should be used when administering to patients with a history of contact sensitivity to nickel (common metal exposure) or if there is a history of vesicular hand eczema (dyshidrosis, pomphylox). Nickel allergy may be confirmed by a positive nickel

patch test. Most patients with hand eczema, positive nickel allergy history, or a positive nickel patch test **do not** have any untoward reaction to administration of ECZEMOL ®. If there is a history of nickel sensitivity or dyshidrotic hand eczema, begin with a very low dose and slowly increase to a recommended starting dose over a period of 5 weeks as tolerated, thus allowing progressive GI absorption *.

***Nickel desensitization schedule:**

Week	Amount of Time to Take Medication Prior to Breakfast
Week 1	**With Breakfast**
Week 2	15 min Prior
Week 3	30 min Prior
Week 4	45 min Prior
Week 5 and thereon	1 hour Prior

If new pruritic rashes occur or persist, discontinue ECZEMOL ® and treat appropriately. **Do not use if there is a history of extra-cutaneous hypersensitivity to nickel or any ingredient in ECZEMOL ®.**

Information for patients

Patients using ECZEMOL ® should receive the following information and instructions:

1. This medication is to be used as directed by a physician.
2. It is important to take orally at the beginning of the day on an empty stomach (or any convenient time after having taken nothing but water for at least 7 hours) and to eat or drink nothing but water for at least one hour afterwards to avoid interference with absorption.

Drug interactions

There are no known drug interactions.

Carcinogenesis, mutagenesis, impairment of fertility

No studies have been done on the carcinogenesis, mutagenesis, or impairment of fertility of ECZEMOL ®. No carcinogenesis or mutagenesis has been reported in multiple animal studies for oral administration of soluble nickel and bromide salts (active ingredients) even at very high doses. [10-14]

Effects of soluble potassium bromide

KBr is not listed as a carcinogen by the NTP, IARC, and OSHA. [16]

Effects of sulphur

Sulphur is not listed as a carcinogen by the ACGIH, IARC, NIOSH, NTP, or OSHA. [25]

Effects of soluble nickel sulphate

Studies on experimental animals have never indicated that nickel, at any dose, is a carcinogen when introduced to the body orally. Furthermore, Nickel sulphate and other highly water soluble nickel salts, have never been known to induce carcinogenesis via any route of introduction including: oral, inhalation, cutaneous, IM, or IP. [10-12,15] No adverse effects were noted on fertility or reproduction in a 3-generational study of albino Wistar rats fed up to 1000 ppm Ni per day, which is equivalent to 50 mg/kg body weight per day Ni. [15]

Pregnancy

Pregnancy category C

Animal reproduction studies have not been conducted with ECZEMOL ®. ECZEMOL ® should not be given to a pregnant woman.

Nursing mothers

It is not known whether this drug is excreted in human milk. However, since many drugs are excreted in human milk, caution should be exercised when ECZEMOL ® is administered to a nursing woman.

Pediatric use

Carefully adjust dosage to weight when treating young children.

ADVERSE REACTIONS

ECZEMOL ® contains low doses of active ingredients. Therefore there are minimal known side effects. (see PRECAUTIONS for hypersensitivity information)

OVERDOSAGE

Potassium bromide toxicity

Indications of toxicity due to oral overdosage of bromide may include nausea, vomiting, apathy, disturbed coordination, loss of memory, drowsiness, loss of emotional control, agitation, hallucination, tremors, depressed reflexes, stupor, and coma. Acute toxic reactions in humans have been reported at doses as low as 1000 mg. [19] This level is 67 times the dose received in one tablet of ECZEMOL ®.

Sulphur toxicity

The oral rat LD_{50} for sulphur is reported to be greater than 5,000 mg/kg . [23] This is more than 37,000 times the maximum dose recommended for ECZEMOL ®. (see Dosage) Ingestion of toxic levels of sulphur can cause sore throat, nausea, headache, gastrointestinal irritation, and possibly unconsciousness in severe cases. [24,25] Sulphur poses such a remote risk that it is placed in the lowest toxic category possible, EPA Toxicity Category IV. [23]

Nickel sulphate toxicity

The oral rat LD_{50} for nickel sulphate hexahydrate is 275 mg/kg. [17] Symptoms of toxicity due to oral overdosage of nickel sulphate may include nausea, vomiting, abdominal discomfort, diarrhea, giddiness, lassitude, headaches, cough, and shortness of breath. [18] The lowest observed transitory toxic effects from human ingestion of soluble nickel salts is approximately 8 mg nickel/kg body weight. [18] This is 180 times the maximum dose recommended for ECZEMOL ®. (See below)

DOSAGE AND ADMINISTRATION

Absorption of nickel sulphate is variable among individuals. **For maximum absorption, tablets should be taken orally at the beginning of the day** (or any convenient time after having taken nothing but water for at least 7 hours). Take nothing but water for one hour after taking medication to aid absorption.

Kg	lbs	Starting dose	Max Daily dose
5-11	11-25	¼	½
12-22	26-50	½	1
23-45	51-100	1	2
46-68	101-150	2	4
69-90	151-200	3	6
91+	201+	4	8

In the setting of renal impairment

Dosage should be adjusted and serum nickel and bromide levels should be followed. Steady state trough level should be drawn prior to ingesting the day's dose after one week of dosing or at appropriate intervals. Target trough serum nickel level is 20-40 mcg/L. (Caution: post dose peak levels are unreliable.) Treatment duration depends on the individual. Increase dose as needed on a monthly basis. Try b.i.d. dosing (upon rising and at bedtime) if max dose (see above) is not effective; do not exceed max daily dose.

Maintenance phase

In order to maintain symptomatic relief, medication may be continued at the same or reduced initial phase dose level.

HOW SUPPLIED

Scored tablets, off white in color with green speckles, with **LL and score** imprinted on same side, in child-resistant and tamper-resistant bottles of 100. **NDC 61480-127-05**

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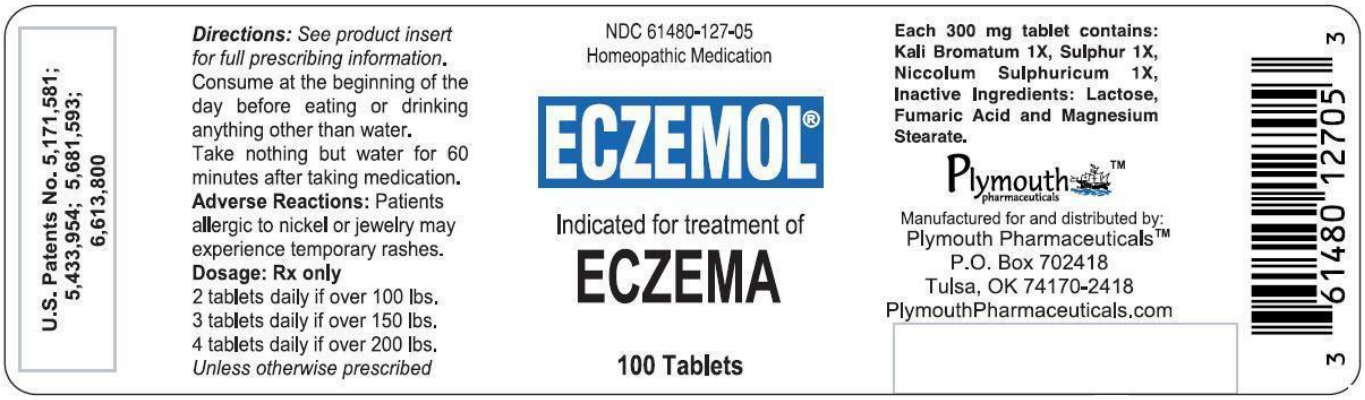
PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

NDC 61480-127-05
Homeopathic Medication

ECZEMOL ®

Indicated for treatment of
ECZEMA

100 Tablets



ECZEMOL

potassium bromide, nickel sulfate, and sulfur tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61480-127
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	1 [hp_X]
NICKEL SULFATE (UNII: 4FLT4T3WUN) (NICKEL CATION - UNII:OIS2CXW7AM)	NICKEL SULFATE	1 [hp_X]
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	1 [hp_X]

Product Characteristics			
Color	white (Off-White with Green Speckles)	**Score**	2 pieces
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	LL

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61480-127-05	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/15/2001	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/15/2001	

Labeler - PLYMOUTH HEALTHCARE PRODUCTS LLC (079330314)

Revised: 11/2022 PLYMOUTH HEALTHCARE PRODUCTS LLC