89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

SAFETY DATA SHEET

Date: 06/26/2024
Generic Name: Naproxen and Esomeprazole Magnesium Delayed-Release Tablets
Brand Equivalent: VIMOVO

SECTION 1: IDENTIFICATION	
Product Name	Naproxen and Esomeprazole Magnesium Delayed-Release Tablets
Active substance	Naproxen and Esomeprazole Magnesium
Synonyms	N/A
Formula	Naproxen: $C_{14}H_{14}O_3$ Esomeprazole Magnesium: $C_{34}H_{36}MgN_6O_6S_2$
Intended Use	Osteoarthritis, Rheumatoid arthritis and Ankylosing spondylitis in adults and Juvenile Idiopathic Arthritis (JIA) in adolescent patients
Chemical Name	Naproxen: (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid Esomeprazole Magnesium: 5-methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]benzimidazole, magnesium salt (2:1)
How Supplied	375 mg/ 20 mg & 500 mg/ 20 mg Yellow, oval shaped, film coated tablets imprinted with 437 on one side for 375/20 mg and imprinting with 438 on one side for 500/20 mg.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723
2. HAZARDS IDENTIFICATION	
Fire and Explosion	Expected to be non-combustible
Environment	Not considered hazardous when handled under normal conditions.
Health	Naproxen and esomeprazole magnesium delayed-release tablets are contraindicated in the following patients: i) History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients. ii) Contraindicated in patients receiving rilpivirine-containing products. iii) Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to naproxen, esomeprazole magnesium, substituted benzimidazole, or to any components of the drug product, including omeprazole. Hypersensitivity reactions to esomeprazole may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria.

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3. COMPOSITION / INFORMATION ON INGREDIENTS		
Components	**CAS-No**	**Concentration (% w/w)**
Naproxen, USP	22204531	90.78 %
Esomeprazole Magnesium Tri-hydrate, USP	217087097	3.921 %
Croscarmellose Sodium, NF (VIVASOL® GF)	74811657	*
Povidone, USP (Kollidon 90F)	25086899	*
Colloidal Silicon Dioxide, NF (Aerosil 200 Pharma)	7631869	*
Magnesium Stearate, NF	557040	*
Hypromellose, USP (Methocel E5 Pr. Lv)	9004653	*
Talc, USP (140)	14807966	*
Methacrylic acid and ethyl acrylate copolymer dispersion, NF (Ecopol L30 D55)	25212888	*
Plasacryl HTP 20	9073603	*
Magnesium oxide, USP (Light)	1309484	*
Polysorbate 80, NF (Tween 80 LQ (MH))	9225656	*
Opadry Yellow (03F82726) Hypromellose, USP 6cps/HPMC 2910 Macrogol/PEG, 6000, NF Titanium Dioxide, USP Talc, USP Iron oxide Yellow	 9004653 25322683 13463677 14807966 51274001	*
* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.		

4. FIRST AID MEASURES	
Ingestion	Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Do not induce vomiting. Call a physician
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance. Get medical attention immediately if symptoms occur.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin irritation occurs.
Eye Contact	Flush eyes with plenty of water. Get medical attention if irritation develops and persists. Do not rub affected area.
Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	There is no clinical data on overdosage with naproxen and esomeprazole magnesium delayed-release tablets. **Overdosage of naproxen:** Symptoms following acute NSAID overdosages have been typically

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	limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which have been generally reversible with supportive care. Gastrointestinal bleeding has occurred. Hypertension, acute renal failure, respiratory depression, and coma have occurred but were rare. A few patients have experienced seizures, but it is not clear whether or not these were drug- related. It is not known what dose of the drug would be life threatening. The oral LD50 of the drug is 500 mg/kg in rats, 1200 mg/kg in mice, 4000 mg/kg in hamsters and greater than 1000 mg/kg in dogs. In animals 0.5 g/kg of activated charcoal was effective in reducing plasma levels of naproxen. Manage patients with symptomatic and supportive care following an NSAID overdosage. There are no specific antidotes. Hemodialysis does not decrease the plasma concentration of naproxen because of the high degree of its protein binding. Consider emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 grams per kg of body weight in pediatric patients) and/or osmotic cathartic in symptomatic patients seen within four hours of ingestion or in patients with a large overdosage (5 to 10 times the recommended dosage). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding. **Overdosage of esomeprazole:** A single oral dose of esomeprazole at 510 mg/kg (about 124 times the human dose on a body surface area basis) was lethal to rats. The major signs of acute toxicity were reduced motor activity, changes in respiratory frequency, tremor, ataxia, and intermittent clonic convulsions. The symptoms described in connection with deliberate esomeprazole overdose (limited experience of doses in excess of 240 mg/day) are transient. Single doses of 80 mg of esomeprazole were uneventful. Reports of overdosage with omeprazole in humans may also be relevant. Doses ranged up to 2,400 mg (120 times the usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience (see omeprazole package insert - Adverse Reactions). No specific antidote for esomeprazole is known. Since esomeprazole is extensively protein bound, it is not expected to be removed by dialysis. In the event of overdosage, treatment should be symptomatic and supportive. If over-exposure occurs, call your Poison Control Center at 1-800-222-1222 for current information on the management of poisoning or overdosage

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5. FIRE-FIGHTING MEASURES	
Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Suitable extinguishing media	Extinguish fires with CO2, extinguishing powder, foam, Dry sand or Water spray.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Special Fire Fighting Procedures	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gears. Use personal protection equipment.
6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Avoid contact with skin, eyes or clothing.
Measures for Environmental Protections	Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Sweep up and shovel into suitable containers for disposal
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.
7. HANDLING AND STORAGE	
Precautions for safe Handling	Avoid all contact and inhalation of dust, mist and vapors associated with the material. Clean equipment and work surface area with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice
Storage Conditions	Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Store in the original container and keep the bottle tightly closed to protect from moisture. Dispense in a tight container if package is subdivided.
8. EXPOSURE CONTROLS/ PERSONNEL PROTECTION	
Eye/ Face protection	If splashes are likely to occur. Wear safety glasses with side shields (or goggles). None required for consumer use.
Skin and body protection	For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

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9. PHYSICAL AND CHEMICAL PROPERTIES		
General Information	**Naproxen**	**Esomeprazole Magnesium**
Molecular Formula	$C_{14}H_{14}O_3$	$C_{34}H_{42}MgN_6O_9S_2$
Odor **Odor** **Odor Threshold**	Not Available	Not Available
pH	10.5	10.0
Other information **Bulk density**	0.301 g/ml	0.183 g/ml
Evaporation rate	Not Available	Not Available
Hydrolysis/Photolysis	Not Available	Not Available
Hygroscopicity	Non-Hygroscopic	Non-Hygroscopic
Molecular Weight	230.26 g/mol	345.42 g/mol
Log Octanol/Water Partition Coeff [log Kow]	3.18	3.49
Surface Tension	Not Available	Not Available
pKa	4.15	4.77
Solubility, Water	15.9 mg/L at 25 °C	17.4 mg/L at 25 °C
Specific Gravity/ Relative Density	Not Available	Not Available
Viscosity	Not Available	Not Available
% Volatile	Not Available	Not Available
Thermal/Stability properties **Autoignition temperature**	Not Available	Not Available
Boiling Point	Not Available	Not Available
Thermal decomposition	Not Available	Not Available
Explosive Limits, LEL **Explosive limits, UEL**	Not Available	Not Available
Explosiveness	Not Available	Not Available
Flammability	Not Available	Not Available
Flash point		
Melting Point	153°C	155°C
Oxidizing Potential	Not Available	Not Available
Vapor Properties **Vapor Density**	Not Available	Not Available
Vapor Pressure	Not Available	Not Available
Saturated Vapor Concentration	Not Available	Not Available

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10. STABILITY AND REACTIVITY	
Stability and Reactivity	Stable under recommended storage conditions. No dangerous reaction known under conditions of normal use.
11. TOXICOLOGICAL INFORMATION	
Carcinogenesis, Mutagenesis &Impairment of Fertility	A 2-year study was performed in rats to evaluate the carcinogenic potential of naproxen at rat doses of 8, 16, and 24 mg/kg/day (0.05, 0.1, and 0.16 times the maximum recommended human daily dose of 1500 mg/day based on a body surface area comparison). The maximum dose used was 0.28 times the highest recommended human dose. No evidence of tumorigenicity was found. The carcinogenic potential of esomeprazole was assessed using omeprazole studies, of which esomeprazole is an enantiomer. In two 24-month oral carcinogenicity studies in rats, omeprazole at daily doses of 1.7, 3.4, 13.8, 44 and 140.8 mg/kg/day (about 0.41 to 34.2 times the human dose of 40 mg/day expressed on a body surface area basis) produced gastric ECL cell carcinoids in a dose-related manner in both male and female rats; the incidence of this effect was markedly higher n female rats, which had higher blood levels of omeprazole. Gastric carcinoids seldom occur in the untreated rat. In addition, ECL cell hyperplasia was present in all treated groups of both sexes. In one of these studies, female rats were treated with 13.8 mg omeprazole/kg/day (about 3.36 times the human dose of 40 mg/day on a body surface area basis) for 1 year, then followed for an additional year without the drug. No carcinoids were seen in these rats. An increased incidence of treatment-related ECL cell hyperplasia was observed at the end of 1 year (94% treated vs 10% controls). By the second year the difference between treated and control rats was much smaller (46% vs 26%) but still showed more hyperplasia in the treated group. Gastric adenocarcinoma was seen in one rat (2%). No similar tumor was seen in male or female rats treated for 2 years. For this strain of rat no similar tumor has been noted historically, but a finding involving only one tumor is difficult to interpret. A 78-week mouse carcinogenicity study of omeprazole did not show increased tumor occurrence, but the study was not conclusive. Esomeprazole was negative in the Ames mutation test, in the in vivo rat bone marrow cell chromosome aberration test, and the in vivo mouse micronucleus test. Esomeprazole, however, was positive in the in vitro human lymphocyte chromosome aberration test. Omeprazole was positive in the in vitro human lymphocyte chromosome aberration test, the in vivo mouse bone marrow cell chromosome aberration test, and the in vivo mouse micronucleus test. The potential effects of esomeprazole on fertility and reproductive performance were assessed using omeprazole studies. Omeprazole at oral doses up to 138 mg/kg/day in rats (about 33.6 times the human dose of

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	40 mg/day on a body surface area basis) was found to have no effect on reproductive performance of parental animals. Studies to evaluate the impact of naproxen on male or female fertility have not been completed.

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

Incinerate in an approved facility. Follow all federal state and local environmental regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations. Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. TRANSPORT INFORMATION

DOT	Not Regulated
IMDG	Not Regulated
ICAO/IATA	Not Regulated
IMO	Not Regulated

15. REGULATORY INFORMATION

This section contains information relevant to compliance with other Federal and/or state laws.

16. OTHER INFORMATION

Recommended Restrictions for Use:	Not available
Prepared on	*06/26/2024*
Revision	00
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