

Safety Data Sheet

Ketoconazole Shampoo 2%

Strength: 2 %

Pack Size: 120 ml
(4 FL OZ) HDPE bottle

NDC 72578-156- 12

Revision No.: 00

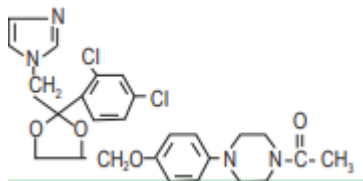
Emergency Overview

Ketoconazole shampoo, 2% is a red-orange liquid for topical application, containing the broad spectrum synthetic antifungal agent ketoconazole in a concentration of 2% in an aqueous suspension. It also contains: cocodiethanolamide, disodium laureth sulfosuccinate, FD&C red no. 40, hydrochloric acid, imidurea, laurdimonium hydroxypropyl hydrolyzed animal collagen, PEG-120 methyl glucose dioleate, purified water, sodium chloride, sodium hydroxide and sodium lauryl ether sulfate.

Section 1: Identification

Product Name: Ketoconazole Shampoo 2%

Chemical Name: Ketoconazole is cis-1-acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine and has the following structural formula::



Description: Ketoconazole shampoo, 2% is a red-orange liquid for topical application, containing the broad spectrum synthetic antifungal agent ketoconazole in a concentration of 2% in an aqueous suspension. It also contains: cocodiethanolamide, disodium laureth sulfosuccinate, FD&C red no. 40, hydrochloric acid, imidurea, laurdimonium hydroxypropyl hydrolyzed animal collagen, PEG-120 methyl glucose dioleate, purified water, sodium chloride, sodium hydroxide and sodium lauryl ether sulfate.

Dosage forms and strengths: Apply the shampoo to the damp skin of the affected area and a wide margin surrounding this area. Lather, leave in place for 5 minutes and then rinse off with water. One application of the shampoo should be sufficient.

Manufacturer / supplier identification

Company

M/S. ZYDUS LIFESCIENCES LIMITED

Address

PLOT NOS. 254-255,
SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 8A,
CHANGODAR, TAL - SANAND,
DIST. AHMEDABAD - 382210,
GUJARAT, INDIA

Contact for information

Tel.+91 2717-616430 Fax: +91 2717-616430

Emergency Telephone No

Tel.+91 2717-616401

Safety Data Sheet**Ketoconazole Shampoo 2%****Strength: 2 %****Pack Size:** 120 ml
(4 FL OZ) HDPE bottle**NDC** 72578-156- 12**Revision No.:** 00**Recommended use / Therapeutic:** Shampoo for prescription use only.
Category**Restriction on Use/:** Use only as directed.
Contraindications**Section 2: Hazard (s) Identification****Classification:**

Physical	Health
Not hazardous	Eye Irritant Category 2 Reproductive Toxicity Category 1B Specific Target Organ Toxicity Category 2 (liver)

Label Elements:**Warning!****Hazard statement(s)**

Causes serious eye irritation.
May damage fertility or the unborn child.
May cause damage to liver through prolonged or repeated exposure.

Precautionary statement(s)

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe mists or spray.

Precautionary statement(s)

Wear eye protection and protective gloves.
Wash hands thoroughly after handling.
IF in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

Section 3: Composition / information on ingredients

Chemical name	CAS No.	Concentration
Ketoconazole	65277-42-1	2%
Coconut fatty acid diethanolamide	61791-31-9	Proprietary
Disodium laureth sulfosuccinate	26468-80-4	Proprietary
FD & C Red No. 40	25956-17-6	Proprietary
Hydrochloric acid	7647-01-0	Proprietary
Imidurea	39236-46-9	Proprietary
Laurdimonium hydroxypropyl hydrolyzed collagen	87914-08-7	Proprietary
PEG-120 methyl glucose dioleate	86893-19-8	Proprietary
Water	7732-18-5	Proprietary
Sodium chloride	7647-14-5	Proprietary

Safety Data Sheet

Ketoconazole Shampoo 2%

Strength: 2 %

Pack Size: 120 ml
(4 FL OZ) HDPE bottle

NDC 72578-156- 12

Revision No.: 00

Sodium hydroxide	1310-73-2	Proprietary
Sodium lauryl ether sulfate	9004-82-4	Proprietary

Section 4: First -aid measures

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: This product is intended for use on the hair and skin. If irritation develops and persists, discontinue use and get medical attention. Remove and contaminated clothing and launder it before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for at least 15 minutes. Remove contact lenses if present and easy to do, then continue rinsing. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

Most important symptoms/effects, acute and delayed: Causes eye irritation. May cause skin irritation.

Ingestion may cause gastrointestinal distress. Occasional allergic reactions have been observed. May cause adverse effects on reproduction.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for ingestion. Ketoconazole Shampoo, 2% is intended for external use only. In the event of accidental ingestion, supportive measures should be employed. Induced emesis and gastric lavage should usually be avoided.

Section 5: Fire -fighting measures

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but may burn in a fire after the water have evaporated.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

Section 6: Accidental Release Measures

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly

Safety Data Sheet

Ketoconazole Shampoo 2%

Strength: 2 %

Pack Size: 120 ml
(4 FL OZ) HDPE bottle

NDC 72578-156- 12

Revision No.: 00

Section 7: Handling and Storage

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging. Do not store above 25°C. Protect from light and heat.

Section 8: Exposure controls/personal protection

Exposure guidelines:

Ketoconazole	100 ug/m3 TWA Perrigo OEL
Coconut fatty acid diethanolamide	None Established
Disodium laureth sulfosuccinate	None Established
FD & C Red No. 40	None Established
Hydrochloric acid	2 ppm Ceiling ACGIH TLV 5 ppm Ceiling OSHA PEL
Imidurea	None Established
Laurdimonium hydroxypropyl hydrolyzed collagen	None Established
PEG-120 methyl glucose dioleate	None Established
Water	None Established
Sodium chloride	None Established
Sodium hydroxide	2 mg/m3 Ceiling ACGIH TLV 2 mg/m3 TWA OSHA PEL
Sodium lauryl ether sulfate	None Established

Appropriate engineering controls: No special ventilation required for normal use. Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: This product is intended for use on the skin and hair. Impervious gloves recommended for handling this product other than for use.

Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.

Other: None known.

Section 9: Physical and chemical properties

Appearance (physical state, color, etc.): Viscous orange to red liquid.

Odor: Odorless

Odor threshold: Not applicable	pH: 6-8
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: None	Evaporation rate: Same as water
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: None	UEL: None

Safety Data Sheet

Ketoconazole Shampoo 2%

Strength: 2 %

Pack Size: 120 ml
(4 FL OZ) HDPE bottle

NDC 72578-156- 12

Revision No.: 00

Vapor pressure: Same as water	Vapor density: Same as water
Relative density: 1.022	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: 1000-15000 cps

Section 10: Stability and reactivity

Reactivity	Not reactive under normal conditions of use.
Chemical stability	Stable
Possibility of hazardous reactions	None known
Conditions to avoid	Avoid excessive heat.
Incompatible materials	Avoid oxidizing agents.
Hazardous decomposition products	Thermal decomposition may yield carbon, sulfur and nitrogen oxides.

Section 11: Toxicological information

Acute effects of exposure:

Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing may cause gastrointestinal distress with nausea and diarrhea.

Skin contact: No adverse effects are expected. Some users have reported skin burning and irritation.

Eye contact: Contact may cause irritation with pain, redness and tearing.

Chronic Effects: Liver effects including hepatitis have been observed in patients taking ketoconazole orally.

Sensitization: Components are not known to be sensitizers. Occasional allergic reactions have been reported.

Germ Cell Mutagenicity: No adverse effects are expected. Components are not germ cell mutagens. The dominant lethal mutation test in male and female mice revealed that single oral doses of ketoconazole as high as 80 mg/kg were not genotoxic. The Ames Salmonella microsomal activator assay was also negative.

Reproductive Toxicity: Ketoconazole has been shown to be teratogenic (syndactylia and oligodactylia) in the rat when given orally in the diet at 80 mg/kg/day (a dose 10 times the maximum recommended human oral dose). However, these effects may be related to maternal toxicity, which was seen at this and higher dose levels. Oligospermia and, rarely, azoospermia have been reported in adult male rats receiving ketoconazole dosages greater than 400 mg daily. A significant decline in sperm motility as well as reductions in sperm density were found at an oral dose of 400 mg/kg administered for a period of 60 days /in mice. Fertility in these mice was greatly reduced compared to that of controls. In a study of the effect of ketoconazole on early pregnancy, rats were treated with 10-100 mg/kg ketoconazole on days 1-8 of pregnancy. Evaluations at gestational day 9 showed a significant reduction in the number of implantation sites and serum progesterone levels as well as increases in uterine body weight. In humans, ketoconazole is not detected in plasma after chronic shampooing of the scalp.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA. A long-term feeding study of ketoconazole in Swiss Albino mice and in Wistar rats showed no evidence of oncogenic activity.

Safety Data Sheet

Ketoconazole Shampoo 2%

Strength: 2 %

Pack Size: 120 ml
(4 FL OZ) HDPE bottle

NDC 72578-156- 12

Revision No.: 00

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 11,364 mg/kg Ketoconazole:
LD50 oral rat 227 mg/kg

Coconut fatty acid diethanolamide: LD50 oral rat >5000 mg/kg

Disodium laureth sulfosuccinate: LD50 oral rat >3000 mg/kg

Section 12: Ecological information

May be harmful to aquatic organisms with long-lasting effects.

Ecotoxicity values: Ketoconazole is classified in the EU as very toxic to aquatic organisms.

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

Section 13: Disposal consideration

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

Section 14: Transport information

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

Section 15: Regulatory information

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Acute Health, Chronic Health

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313: None

EPA TSCA Inventory: This product is a drug and not subject to TSCA. CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

Canadian WHMIS Classification: Drugs are exempt from WHMIS

Safety Data Sheet**Ketoconazole Shampoo 2%****Strength: 2 %****Pack Size:** 120 ml
(4 FL OZ) HDPE bottle**NDC** 72578-156- 12**Revision No.:** 00

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

Section 16: Other information**NFPA Rating:** Health = 1 Flammability = 0 Instability = 0**HMIS Rating:** Health = 2* Flammability = 0 Physical Hazard = 0**SDS Revision History:** Corrected Hazard Classification in Section 2

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

Date of issue: 22/08/24**Supersedes edition:** N/A