SAFETY DATA SHEETS

This SDS packet was issued with item:

078866723

N/A

Material Safety Data Sheet

CLINDAMYCIN HYDROCHLORIDE CAPSULES
(150 mg / 300 mg)

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING	
Material	Clindamycin Hydrochloride
Empirical Chemical Formula	$C_{18}H_{33}ClN_2O_5 \bullet HCl$
Synonyms	Cleocin, Dalacin
Manufacturer	Ohm Laboratories, Inc., 1385 Livingston Ave. North Brunswick, NJ, 08907, USA.
Distributor	Ranbaxy Pharmaceuticals Inc., 9431, Florida Mining Blvd. East, Jacksonville, FL, 32257

2. COMPOSITION / INFORMATION ON INGREDIENTS		
Ingredients	CAS Number	Percentage
Clindamycin	21462-39-5	150 /300 mg - 59.2%
Non-Hazardous Ingredients	–	150/300 mg - 40.8%

3. HAZARDS IDENTIFICATION	
Fire and Explosion	Expected to be non-combustible.
Health	May cause allergic reaction. May cause eye irritation Active ingredient is not a skin irritant; Not acutely toxic (based on animal data). Adverse effects associated with the therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Pseudo membranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.
Environment	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

4. FIRST-AID MEASURES	
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
NOTES TO PHYSICIANS / HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Antidotes	No specific antidote exists.

5. FIRE-FIGHTING MEASURES	
Fire and Explosion Hazards	Not expected for the product.
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Special Firefighting Procedures	During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen, sulfur, and chlorine.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Methods	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Decontamination Procedure	No specific decontamination or detoxification procedures have been identified for this product.
7. HANDLING AND STORAGE	
Safe Handling and	Minimize dust generation and accumulation. If capsules are crushed and/or

Use	broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment.
Storage	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
PERSONAL PROTECTIVE EQUIPMENT	
Eye Protection	Wear safety glasses or goggles if eye contact is possible.
Respirators	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Other Equipment or Procedures	Wear appropriate clothing to avoid skin contact.
Work / Hygienic Practices	Instruction of employees mandatory. Shower after work recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Physical Form (Appearance)	Shape & Color (150 mg) – White to off-white powder filled in Size 1 blue opaque cap/light green body hard gelatin capsules Shape & Color (300 mg) – White to off-white powder filled in Size 0 turquoise blue opaque cap/ turquoise blue opaque body hard gelatin capsules

10. STABILITY AND REACTIVITY	
Stability	Stable
Conditions to Avoid	n/k, as a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION	
This product contains active pharmaceutical ingredient Clindamycine hydrochloride, the specific information on which is provided below.	
Oral Toxicity	One year oral toxicity studies in Spartan Sprague-Dawley rats and beagle dogs at dose levels up to 300 mg/kg/day (approximately 1.6 and 5.4 times the highest recommended adult human dose based on mg/m2, respectively) have shown

	clindamycin to be well tolerated. No appreciable difference in pathological findings has been observed between groups of animals treated with clindamycin and comparable control groups. Rats receiving clindamycin hydrochloride at 600 mg/kg/day (approximately 3.2 times the highest recommended adult human dose based on mg/m2) for 6 months tolerated the drug well; however, dogs dosed at this level (approximately 10.8 times the highest recommended adult human dose based on mg/m2) vomited, would not eat, and lost weight.
Inhalation Toxicity	n/k
Skin Effects	Pruritus, vaginitis, and rare instances of exfoliative dermatitis have been reported.
Eye Effects	May cause eye irritation
Target Organ Effects	*Liver:* Jaundice and abnormalities in liver function tests have been observed during clindamycin therapy. *Renal:* Although no direct relationship of clindamycin to renal damage has been established, renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria has been observed in rare instances. *Hematopoietic:* Transient neutropenia (leukopenia) and eosinophilia have been reported. Reports of agranulocytosis and thrombocytopenia have been made. No direct etiologic relationship to concurrent clindamycin therapy could be made in any of the foregoing. *Musculoskeletal:* Rare instances of polyarthritis have been reported
Sensitisation	May cause sensitization by skin contact
Genetic Toxicity	Genotoxicity tests performed included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative.
Carcinogenicity	Long term studies in animals have not been performed with clindamycin to evaluate carcinogenic potential
Reproductive Effects	Reproduction studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (3.2 and 1.6 times the highest recommended adult human dose based on mg/m2, respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (1.3 and 0.7 times the highest recommended adult human dose based on mg/m2, respectively) revealed no evidence of teratogenicity. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of the human response, this drug should be used during pregnancy only if clearly

	needed. Clindamycin has been reported to appear in breast milk in the range of 0.7 to 3.8 mcg/mL When Clindamycin HCl is administered to the pediatric population (birth to 16 years), appropriate monitoring of organ system functions is desirable.
Gastrointestinal Reactions	Abdominal pain, pseudo membranous colitis, esophagitis, nausea, vomiting and diarrhea. The onset of pseudo membranous colitis symptoms may occur during or after antibacterial treatment.
Hypersensitivity Reactions	Generalized mild to moderate morbilliform-like (maculopapular) skin rashes are the most frequently reported adverse reactions. Vesiculobullous rashes, as well as urticaria, have been observed during drug therapy. Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, and a few cases of anaphylactoid reactions have also been reported.
Pharmacological Effects	Serum level studies with a 150 mg oral dose of Clindamycin hydrochloride in 24 normal adult volunteers showed that clindamycin was rapidly absorbed after oral administration. An average peak serum level of 2.50 mcg/mL was reached in 45 minutes; serum levels averaged 1.51 mcg/mL at 3 hours and 0.70 mcg/mL at 6 hours. Absorption of an oral dose is virtually complete (90%), and the concomitant administration of food does not appreciably modify the serum concentrations; serum levels have been uniform and predictable from person to person and dose to dose. Serum level studies following multiple doses of Clindamycin HCl for up to 14 days show no evidence of accumulation or altered metabolism of drug. Serum half-life of clindamycin is increased slightly in patients with markedly reduced renal function. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum. Concentrations of clindamycin in the serum increased linearly with increased dose. Serum levels exceed the MIC (minimum inhibitory concentration) for most indicated organisms for at least six hours following administration of the usually recommended doses. Clindamycin is widely distributed in body fluids and tissues (including bones). The average biological half-life is 2.4 hours. Approximately 10% of the bioactivity is excreted in the urine and 3.6% in the feces; the remainder is excreted as bioinactive metabolites. Doses of up to 2 grams of clindamycin per day for 14 days have been well tolerated by healthy volunteers, except that the incidence of gastrointestinal side effects is greater with the higher doses. No significant levels of clindamycin are attained in the cerebrospinal fluid, even in the presence of inflamed meninges.

	Pharmacokinetic studies in elderly volunteers (61–79 years) and younger adults (18–39 years) indicate that age alone does not alter clindamycin pharmacokinetics (clearance, elimination half-life, volume of distribution, and area under the serum concentration-time curve) after IV administration of clindamycin phosphate. After oral administration of clindamycin hydrochloride, elimination half-life is increased to approximately 4.0 hours (range 3.4–5.1 h) in the elderly compared to 3.2 hours (range 2.1 – 4.2 h) in younger adults. The extent of absorption, however, is not different between age groups and no dosage alteration is necessary for the elderly with normal hepatic function and normal (age-adjusted) renal function.
Over Dosage	Significant mortality was observed in mice at an intravenous dose of 855 mg/kg and in rats at an oral or subcutaneous dose of approximately 2618 mg/kg. In the mice, convulsions and depression were observed. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.
Contraindications	Clindamycin HCl is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.
Other Information	n/k

12. ECOLOGICAL INFORMATION
This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.
Do not allow product to enter drinking water supplies, waste water or soil.

13. DISPOSAL CONSIDERATIONS	
Disposal Recommendations	Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Collect for recycling or recovery if possible. The disposal method for rejected Products /returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The MSDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.	
Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION	
EU Classification and Labelling	Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.
US OSHA Standard (29 CFR Part 1910.1200)	This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.
OTHER US REGULATIONS	
	Exempt

16. OTHER INFORMATION

The above information and recommendations are believed to be correct as on date but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ranbaxy shall not be held liable for any damage resulting from handling or from contact with the above product. Ranbaxy reserves the right to revise this MSDS.

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING	
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Synonyms	Cleocin, Dalacin
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2. COMPOSITION / INFORMATION ON INGREDIENTS		
Ingredients	CAS Number	Percentage
Clindamycin	21462-39-5	150 /300 mg - 59.2%
Non-Hazardous Ingredients	–	150/300 mg - 40.8%

3. HAZARDS IDENTIFICATION	
Fire and Explosion	Expected to be non-combustible.
Health	May cause allergic reaction. May cause eye irritation Active ingredient is not a skin irritant; Not acutely toxic (based on animal data). Adverse effects associated with the therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Pseudo membranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.
Environment	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

4. FIRST-AID MEASURES	
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
NOTES TO PHYSICIANS / HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Antidotes	No specific antidote exists.

5. FIRE-FIGHTING MEASURES	
Fire and Explosion Hazards	Not expected for the product.
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Special Firefighting Procedures	During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen, sulfur, and chlorine.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Methods	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Decontamination Procedure	No specific decontamination or detoxification procedures have been identified for this product.
7. HANDLING AND STORAGE	
Safe Handling and	Minimize dust generation and accumulation. If capsules are crushed and/or

Use	broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment.
Storage	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
PERSONAL PROTECTIVE EQUIPMENT	
Eye Protection	Wear safety glasses or goggles if eye contact is possible.
Respirators	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Other Equipment or Procedures	Wear appropriate clothing to avoid skin contact.
Work / Hygienic Practices	Instruction of employees mandatory. Shower after work recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Physical Form (Appearance)	Shape & Color (150 mg) – White to off-white powder filled in Size 1 blue opaque cap/light green body hard gelatin capsules Shape & Color (300 mg) – White to off-white powder filled in Size 0 turquoise blue opaque cap/ turquoise blue opaque body hard gelatin capsules

10. STABILITY AND REACTIVITY	
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Conditions to Avoid	n/k, as a precautionary measure, keep away from strong oxidizers.

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Skin Effects	Pruritus, vaginitis, and rare instances of exfoliative dermatitis have been reported.
Eye Effects	May cause eye irritation
Target Organ Effects	*Liver:* Jaundice and abnormalities in liver function tests have been observed during clindamycin therapy. *Renal:* Although no direct relationship of clindamycin to renal damage has been established, renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria has been observed in rare instances. *Hematopoietic:* Transient neutropenia (leukopenia) and eosinophilia have been reported. Reports of agranulocytosis and thrombocytopenia have been made. No direct etiologic relationship to concurrent clindamycin therapy could be made in any of the foregoing. *Musculoskeletal:* Rare instances of polyarthritis have been reported
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Carcinogenicity	Long term studies in animals have not been performed with clindamycin to evaluate carcinogenic potential
Reproductive Effects	Reproduction studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (3.2 and 1.6 times the highest recommended adult human dose based on mg/m2, respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (1.3 and 0.7 times the highest recommended adult human dose based on mg/m2, respectively) revealed no evidence of teratogenicity. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of the human response, this drug should be used during pregnancy only if clearly

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Gastrointestinal Reactions	Abdominal pain, pseudo membranous colitis, esophagitis, nausea, vomiting and diarrhea. The onset of pseudo membranous colitis symptoms may occur during or after antibacterial treatment.
Hypersensitivity Reactions	Generalized mild to moderate morbilliform-like (maculopapular) skin rashes are the most frequently reported adverse reactions. Vesiculobullous rashes, as well as urticaria, have been observed during drug therapy. Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, and a few cases of anaphylactoid reactions have also been reported.
Pharmacological Effects	Serum level studies with a 150 mg oral dose of Clindamycin hydrochloride in 24 normal adult volunteers showed that clindamycin was rapidly absorbed after oral administration. An average peak serum level of 2.50 mcg/mL was reached in 45 minutes; serum levels averaged 1.51 mcg/mL at 3 hours and 0.70 mcg/mL at 6 hours. Absorption of an oral dose is virtually complete (90%), and the concomitant administration of food does not appreciably modify the serum concentrations; serum levels have been uniform and predictable from person to person and dose to dose. Serum level studies following multiple doses of Clindamycin HCl for up to 14 days show no evidence of accumulation or altered metabolism of drug. Serum half-life of clindamycin is increased slightly in patients with markedly reduced renal function. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum. Concentrations of clindamycin in the serum increased linearly with increased dose. Serum levels exceed the MIC (minimum inhibitory concentration) for most indicated organisms for at least six hours following administration of the usually recommended doses. Clindamycin is widely distributed in body fluids and tissues (including bones). The average biological half-life is 2.4 hours. Approximately 10% of the bioactivity is excreted in the urine and 3.6% in the feces; the remainder is excreted as bioinactive metabolites. Doses of up to 2 grams of clindamycin per day for 14 days have been well tolerated by healthy volunteers, except that the incidence of gastrointestinal side effects is greater with the higher doses. No significant levels of clindamycin are attained in the cerebrospinal fluid, even in the presence of inflamed meninges.

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Over Dosage	Significant mortality was observed in mice at an intravenous dose of 855 mg/kg and in rats at an oral or subcutaneous dose of approximately 2618 mg/kg. In the mice, convulsions and depression were observed. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.
Contraindications	Clindamycin HCl is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.
Other Information	n/k

12. ECOLOGICAL INFORMATION
This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.
Do not allow product to enter drinking water supplies, waste water or soil.

13. DISPOSAL CONSIDERATIONS	
Disposal Recommendations	Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Collect for recycling or recovery if possible. The disposal method for rejected Products /returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The MSDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.	
Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION	
EU Classification and Labelling	Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.
US OSHA Standard (29 CFR Part 1910.1200)	This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.
OTHER US REGULATIONS	
	Exempt

16. OTHER INFORMATION

The above information and recommendations are believed to be correct as on date but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ranbaxy shall not be held liable for any damage resulting from handling or from contact with the above product. Ranbaxy reserves the right to revise this MSDS.