



TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Medroxyprogesterone Acetate
Injectable Suspension, USP

1. PRODUCT IDENTIFICATION

Product Name Medroxyprogesterone Acetate Injectable Suspension, USP
Product Use Medical Treatment; Prevention of Pregnancy
Manufacturer Teva Parenteral Medicines, Inc.
Address 11 Hughes
 Irvine, CA 92618-1902

Chemtrec Emergency No. 1-800-424-9300 (United States)
 1-202-483-7617 (International Collect)
Business Phone 1-800-729-9991
Website Address <http://www.tevausa.com>

Common Names Medroxyprogesterone acetate
Chemical Name Pregn-4-ene-3, 20-dione, 17-(acetoxy)-6-methyl-, (6 α)-

Chemical Formula C₂₄H₃₄O₄
Chemical Family Steroid
How Supplied 150mg/mL, 1mL in a vial or Pre-filled syringe

Date of Preparation: December 11, 2001/Revision 1: February 20, 2004

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	% by wt	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA		IDLH	OTHER
			TLV	STEL	PEL	STEL		TWA (8-10 h)
Medroxyprogesterone Acetate	71-58-9	15	NE	NE	NE	NE	NE	¹ 5 ug/m ³
Polyethylene Glycol	25322-68-3	2.89	NE	NE	NE	NE	NE	NE
Polysorbate 80	9005-65-6	0.241	NE	NE	NE	NE	NE	NE
Sodium Chloride	7647-14-5	0.868	NE	NE	NE	NE	NE	NE
Methylparaben	99-76-3	0.137	NE	NE	NE	NE	NE	NE
Propylparaben	94-13-3	0.015	NE	NE	NE	NE	NE	NE
Water for Injection	7732-18-5	80.849	NE	NE	NE	NE	NE	NE

1. Paramcia & Upjohn Exposure Limit

Hydrochloric acid and/or sodium hydroxide is used to adjust pH

NE - Not Established

C - Ceiling Limit

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 – 1998 format
 CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Material is a white suspension. Probable cancer hazard. Birth defect hazard. May cause allergic reactions. Avoid exposure during pregnancy. Avoid contact with eyes, skin and clothing. Avoid breathing. Do not taste or swallow. Wash thoroughly after handling.



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3. HAZARD IDENTIFICATION cont.

Symptoms of Overexposure by Route of Exposure: This material is intended for intramuscular injection under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes: Material may be a mild eye and skin irritant. Eye contact may cause stinging, watering, redness, and swelling. May cause discoloration of the skin and an allergic skin reaction (e.g., urticaria, pruritus, angioedema, generalized rash and anaphylaxis). Acne, alopecia or hirsutism are rare.

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, if ingested, symptoms similar to those identified under injection may occur, including menstrual irregularities in women.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure (An explanation in lay terms):

Acute: The primary health effects anticipated in an occupational setting include anaphylaxis and discoloration of the skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, nervousness, insomnia, fatigue, dizziness, abdominal cramps, cholestatic jaundice, headaches, depression, nausea and weight changes. Women may experience menstrual irregularities and breast tenderness.

Chronic: In addition to those effects identified above, prolonged or repeated ingestion of large doses of Medroxyprogesterone Acetate may cause reproductive and thrombotic effects. Gynecomastia (enlarged mammary glands) and reversible decreases in sperm production may occur in men.

Cancer: Medroxyprogesterone Acetate has been identified as a possible carcinogen by IARC (see Section 11).

Target Organs: This product may produce adverse effects on the male and female reproductive systems (see Section 11).

Developmental Toxicity: Medroxyprogesterone Acetate can cause fetal harm if taken during pregnancy (see Section 11).

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include thrombophlebitis, thromboembolic disorders, liver disease, cerebral apoplexy, breast cancer, undiagnosed vaginal bleeding or pregnancy.



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Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Eye Exposure: Move victim away from exposure and into fresh air. If irritation or redness develops, flush eyes with clean water and seek immediate medical attention. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

5. FIRE-FIGHTING MEASURES

Flash Point: No data Autoignition Temperature: No data

Flammable Limits (in air by volume, %): Lower: No data Upper: No data

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK Carbon Dioxide: OK Halon: OK
Foam: OK Dry Chemical: OK Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8).

Special Fire Fighting Procedures cont.: Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

NFPA HAZARD CLASS: Health: 1 (Slight)
 Flammability: 0 (Least)
 Reactivity: 0 (Least)



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6. ACCIDENTAL RELEASE MEASURES

Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay upwind and away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

7. HANDLING and STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from any incompatible materials or conditions (see Section 10). Protect from light.

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.



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Relative Vapor Density (air = 1):	ND	Evaporation Rate (n- Melting/Freezing Point:	<1 ND
Specific Gravity (water = 1):	ND	Boiling Point:	ND
Solubility in Water:	Insoluble	pH:	Target = 6.7 Range = 3.0 –7.0
Vapor Pressure, mm Hg @ 25°C.	ND		
Odor Threshold: ND			
Appearance and Color: White Suspension			

10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility.

Hazardous Polymerization: Will not occur.

Conditions To Avoid: Protect from light and excessive heat.

11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Medroxyprogesterone Acetate

Oral LD50(rat) >6400 mg/kg Subcutaneous LD50(rat) >900 mg/kg IP LD50(rat) > 900 mg/kg
Oral LD50(mouse) >16 g/mg Subcutaneous LD50(mouse) >1500 mg/kg IP LD50(rat) >400 mg/kg
Oral LD50(dog) >5 g/mg IP LD50(mouse) >1500 mg/kg IP (LD50 (mouse) >400 mg/kg
IV LD50(mouse) = 376 mg/kg

Suspected Cancer Agent: Medroxyprogesterone acetate is listed by IARC as a Group 2B carcinogen (possibly carcinogenic to humans). A ten year study of intramuscular injections of medroxyprogesterone acetate in primates (consisting of dosages up to 50 times the human therapeutic dose) showed expected hormonal effects, mammary nodular hyperplasia and endometrial carcinomas in a few of the test animals. There is no evidence that medroxyprogesterone is carcinogenic in humans.

Irritancy of Product: This product may be mildly irritating to eyes and other tissues.

Sensitization to the Product: Hypersensitivity reactions include urticaria, pruritus, angioedema, generalized rash and anaphylaxis.



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11. TOXICOLOGICAL INFORMATION cont.

Reproductive Toxicity Information: Listed below is information concerning the effects of Medroxyprogesterone Acetate on human and animal reproductive systems. This material is classified as a Pregnancy Category X (DO NOT use during pregnancy).

Mutagenicity: Medroxyprogesterone Acetate showed no mutagenic potential in both the Ames assay and micronucleus test.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Treatment of rats with intramuscular doses of up to 30 mg/kg/day of Medroxyprogesterone Acetate showed no teratogenic effects, but several animal studies have shown developmental abnormalities in the fetuses. Masculinization of the female fetus reportedly occurred when progestin was used during pregnancy. Clitoral hypertrophy and fusion of the labia have been reported in female newborns and hypospadias (congenital defect in the anterior urethra) in the male.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Medroxyprogesterone Acetate on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Medroxyprogesterone Acetate on plants or animals in the aquatic environment.

13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

14. TRANSPORTATION INFORMATION

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)



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15. REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Medroxyprogesterone Acetate is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product contains Medroxyprogesterone Acetate a chemical known to the State of California to cause cancer and developmental effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):

CAUTION! PROBABLE CANCER HAZARD. BIRTH DEFECT HAZARD. MAY CAUSE ALLERGIC REACTIONS. Medroxyprogesterone Acetate should be administered under the supervision of a qualified physician. Avoid over-exposure. Avoid exposure during pregnancy. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when handling Medroxyprogesterone Acetate. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: Medroxyprogesterone Acetate is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

16. OTHER INFORMATION

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Previous Issue Date: 2/20/04

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