



Allergan

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: GENERESS FE[®] TABLETS Norethindrone/Ethinyl Estradiol Tablets 0.8 mg/25 mcg and Ferrous Fumarate Tablets

DESCRIPTION: Norethindrone/Ethinyl Estradiol Chewable Tablets and Ferrous Fumarate Chewable Tablets

OTHER DESIGNATIONS: NDC# 0023-6030 -03

CHEMICAL NAME: 17-Hydroxy-19-nor-17 α -pregn-4-en-20-yn-3-one/19-Nor-17 α -pregna-1,3,5 (10)-trien-20-yne-3,17-diol

CHEMICAL FAMILY: Hormone

HOW SUPPLIED: 0.8 mg/25 mcg Tablet

FORMULA: C₂₀H₂₆O₂/C₂₀H₂₄O₂

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:

U.S. ADDRESS:

U.S. BUSINESS PHONE/GENERAL SDS INFORMATION:

Allergan

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1-800-272-5525

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EUROPEAN ADDRESS:

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EMERGENCY PHONE (OUTSIDE U.S.): CHEMTREC: +1-703-527-3887 (24 hours) Outside North America

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: February 14, 2019

DATE OF REVISION:

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

Classification: Not Applicable **Signal Word:** Not Applicable **Hazard Statement Codes:** Not Applicable

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

Classification: Not Applicable **Risk Phrases:** Not Applicable **Safety Phrases:** Not Applicable

See Section 16 for full EU classification information of product and components and full text of hazard and precautionary statements.

EMERGENCY OVERVIEW:

Product Description: This product is supplied as 24 light green, round tablets (active) each containing 0.8 mg norethindrone and 0.025 mg ethinyl estradiol. 4 brown, round tablets (non-hormonal placebo) each containing 75 mg ferrous fumarate.

Health Hazards: The chief health hazard associated with overexposures during normal use and handling is the potential for irritation of contaminated skin. Estrogen-progestogen oral contraceptives (such as this product) are known human carcinogens. Norethindrone combined with Ethinyl Estradiol (the active components in this product) is a reproductive toxin. Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing estrogens and/or progestogens may experience allergic reactions to this product. Therapeutic use of this product can cause adverse symptoms of the cardiac system, pulmonary system, gallbladder, gastrointestinal system, and liver.





Flammability Hazards: If heated to high temperatures for a prolonged period, the product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon monoxide and carbon dioxide).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
ACTIVE INGREDIENTS IN HORMONE TABLET:				
Ethinyl Estradiol	57-63-6	200-342-2	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Toxic Risk Phrases: R45, R49, R60, R61, R48  Hazard Symbol: EU/GHS 1272/2008 Signal word: Danger Classification: Reproductive Toxicity Cat. 1B, Carcinogenic Cat. 1B, Target Organ Toxicity, repeated exposure, category 1 Hazard Statement Codes: H350, H360, H372  Hazard Symbol/Pictogram:
Norethindrone	68-22-4	200-681-6	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Toxic Risk Phrases: R45, R49, R60, R61, R48  Hazard Symbol: EU/GHS 1272/2008 Signal word: Danger Classification: Reproductive Toxicity Cat. 1B, Carcinogenic Cat. 1B, Target Organ Toxicity, repeated exposure, category 1 Hazard Statement Codes: H350, H360, H372  Hazard Symbol/Pictogram:
EXCIPIENTS:				
Dibasic Phosphate	Calcium 7757-93-9	231-826-1	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Lactose	63-42-3	200-559-2	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Maltodextrin	9050-36-6	232-940-4	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Povidone	9003-39-8	Unlisted	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sodium Starch Glycolate	9063-38-1	Unlisted	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sucralose	56038-13-2	259-952-2	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Proprietary Spearmint Flavor				EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
PLACEBO INGREDIENTS:				
Ferrous Fumarate	141-01-5	205-447-7	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Povidone	9003-39-8	Unlisted	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sodium Starch Glycolate	9063-38-1	Unlisted	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sugar, Compressible	64333-34-2	Unlisted	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable

See Section 16 for full EU classification information of product and components.

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

4 FIRST-AID MEASURES (Continued)

IMMEDIATE MEDICAL ATTENTION NEEDED: If Adverse Effect Occurs: Yes. Persons developing hypersensitivity reactions should receive immediate medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.

DESCRIPTION OF FIRST AID MEASURES: Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of label and SDS to physician or other health professional with victim(s).

INHALATION: If dusts or particulates from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

SKIN EXPOSURE: Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

EYE EXPOSURE: If particulates from this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

INGESTION EXPOSURE: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 3 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated overexposures to this product. The following pre-existing conditions may be aggravated by therapeutic doses of this product: Thrombophlebitis or thromboembolic disorders, cerebrovascular or coronary artery disease, carcinoma of the breast, carcinoma of the endometrium, other known or suspected estrogen-dependent neoplasia, undiagnosed abnormal genital bleeding, cholestatic jaundice of pregnancy or jaundice with prior pill use, hepatic adenomas or carcinomas.

IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not determined.

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

UNSUITABLE EXTINGUISHING MEDIA: None known.

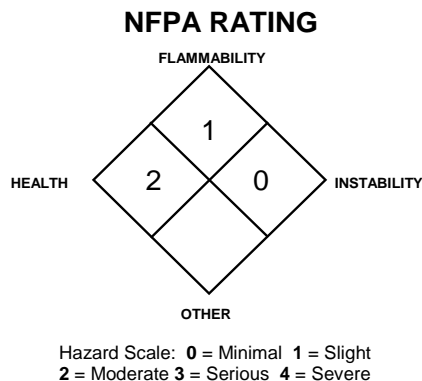
SPECIAL FIRE AND EXPLOSION HAZARDS: This product may ignite if highly heated for a prolonged period of time. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides). This product contains a potential sensitizer and so presents a possible contact hazard to firefighters.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Although this product is not sensitive to

static discharge, finely-divided dusts can be ignited by static discharge with explosive potential. Refer to NFPA 654, *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids*, for comprehensive guidance.

ADVICE TO FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.



6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Monitor area and confirm levels are below exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g., 1 vial of tablets), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., a pallet of vials), protective apparel should be used with a respirator when there is any danger of airborne dusts being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.**

METHODS FOR CLEANUP AND CONTAINMENT:

Small Spills: Pick-up or sweep-up spilled tablets.

Large Spills: Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill areas should be restricted. Sweep up spilled product carefully, avoiding the generation of airborne dusts.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: Employees must be trained to properly use this product. As with all chemicals, avoid getting this material ON YOU or IN YOU.

PRECAUTIONS FOR SAFE HANDLING (continued): Do not eat, drink, smoke, or apply cosmetics in work areas where this product is handled or stored. Wash thoroughly after handling this product or equipment and containers of this product. In manufacturing areas, wipe down areas in which this product is used, so that dusts from this product do not accumulate. Refer to NFPA 654, *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids*, for comprehensive guidance. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Use of this product should be performed in a designated area for working with drugs. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. Use of this product should meet the provisions outlined as follows.

- Work should be performed in an appropriate, designated area;
- Contaminated waste must be properly handled; and,
- If necessary, work areas must be regularly decontaminated.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store this product in original container at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature). Inspect bottles containing this product for leaks or damage. Store away from incompatible materials (see Section 10, Stability and Reactivity).

SPECIFIC END USE(S): This product human pharmaceutical. Follow all industry standards for use of this product.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: Follow practices indicated in Section 6 (Accidental Release Measures). When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and all disposable items contaminated with this product and dispose of according to applicable local, national, and international regulations.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

EXPOSURE LIMITS/CONTROL PARAMETERS:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELS		NIOSH	OTHER
		TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	IDLH mg/m ³	μg/m ³
Ethinyl Estradiol	57-63-6	NE	NE	NE	NE	NE	NE	NE	.01
Norethindrone	68-22-4	NE	NE	NE	NE	NE	NE	NE	NE
Ferrous Fumarate	141-01-5	NE	NE	NE	NE	NE	NE	NE	NE
Calcium Phosphate, Dibasic	7757-93-9	NE	NE	NE	NE	NE	NE	NE	NE
Lactose	63-42-3	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate Limits are for Stearates	557-04-0	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Microcrystalline Cellulose	9004-34-6	10	NE	15 (total dust), 5 (resp. fract.)	NR	10 (total dust), 5 (resp. fract.)	NE	NE	NE
Maltodextrin	9050-36-6	NE	NE	NE	NE	NE	NE	NE	NE
Povidone	9003-39-8	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Starch Glycolate	9063-38-1	NE	NE	NE	NE	NE	NE	NE	NE
Sucralose	56038-13-2	NE	NE	NE	NE	NE	NE	NE	NE
Sugar, Compressible	64333-34-2	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established. See Section 16 for Definitions of Other Terms Used

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: In addition to the exposure limit values cited in this section, other exposure limits have been established by various countries for the components of this product. Below are available limits for the active ingredient and excipient components. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

FERROUS FUMARATE:

Australia: TWA = 0.1 mg(Fe)/m³, JUL 2008
 Belgium: TWA = 1 mg(Fe)/m³, MAR 2002
 Finland: TWA = 1 mg(Fe)/m³, SEP 2009
 Norway: TWA = 1 mg(Fe)/m³, JAN 1999

MAGNESIUM STEARATE:

New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
 Sweden: TWA = 5 mg/m³, JUN 2005

MICROCRYSTALLINE CELLULOSE:

Belgium: TWA = 10 mg/m³, MAR 2002
 France: VME = 10 mg/m³, FEB 2006

MICROCRYSTALLINE CELLULOSE (continued):

Korea: TWA = 10 mg/m³, 2006
 Mexico: TWA = 10 mg/m³; STEL = 20 mg/m³, 2004
 The Netherlands: MAC-TGG = 2 mg/m³, 2003
 New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
 Russia: STEL = 10 mg/m³, JUN 2003
 Switzerland: MAK-W = W 6 mg/m³, DEC 2006
 United Kingdom: TWA = 10 mg/m³ (inhalable), 2005
 United Kingdom: TWA = 4 mg/m³; STEL = 20 mg/m³ (respirable), 2005
 In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam, check ACGIH TLV

POVIDONE:

Russia: STEL = 10 mg/m³, JUN 2003

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132), equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-07), standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Respiratory protection is generally not needed during routine conditions of use of this product.

EYE PROTECTION: No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, splash goggles or safety glasses should be considered.

HAND PROTECTION: During medical administration of this product, gloves should not be necessary. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response as stated in Section 6 (Accidental Release Measures) of this SDS.

BODY PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Tablet.

ODOR: Odorless.

BOILING POINT: Not applicable for product.

EVAPORATION RATE (nBuAc = 1): Not established.

VAPOR PRESSURE (air = 1): Not applicable for product.

COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

COLOR: White and brown.

ODOR THRESHOLD: Not applicable.

FREEZING/MELTING POINT: Not established.

SOLUBILITY IN WATER: Not soluble.

SPECIFIC GRAVITY (water = 1): Not applicable.

pH: Not applicable.

10. STABILITY and REACTIVITY

REACTIVITY/CHEMICAL STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: *Combustion:* If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides). *Hydrolysis:* None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

POSSIBILITY OF HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

INHALATION: Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Although rare, some persons may experience allergic reaction to estrogens and experience anaphylactoid/anaphylactic reactions. Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.

SKIN ABSORPTION: Absorption of airborne particles of hormones through the skin may contribute to the effects of exposure as described in "Other Potential Health Effects".

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices can cause serious ill effects and nausea. Ingestion of high doses of the Norethindrone component of this product may terminate early pregnancy. Symptoms of chronic ingestion caused by poor hygiene practices may include those described for "Other Potential Health Effects".

INJECTION: Though not anticipated to be a significant route of overexposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection.

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included:



- Thrombophlebitis, arterial thromboembolism, pulmonary embolism, myocardial infarction, cerebral hemorrhage, cerebral thrombosis, high blood pressure, gallbladder disease, and hepatic adenomas or benign liver tumors.
- Mesenteric thrombosis and retinal thrombosis.
- Nausea, vomiting, gastrointestinal symptoms (such as abdominal cramps and bloating), breakthrough bleeding, spotting, change in menstrual flow, cessation of periods, temporary infertility after discontinuation of treatment, swelling, melasma that may persist, breast changes (tenderness, enlargement, secretion), changes in weight, changes in cervical erosion and secretion, diminution in lactation when given immediately postpartum, cholestatic jaundice, migraine, allergic rash, mental depression, reduced tolerance to carbohydrates, vaginal candidiasis, change in corneal curvature, and intolerance to contact lenses.
- Premenstrual syndrome, cataracts, optic neuritis, changes in appetite, cystitis-like syndrome, headache, nervousness, dizziness, hirsutism, loss of scalp hair, erythema multiforme, erythema nodosum, hemorrhagic eruption, vaginitis, porphyria, impaired renal function, hemolytic uremic syndrome, Budd-Chiari syndrome, acne, changes in libido, and colitis.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Acute ingestion of large quantities of this product caused by poor hygiene practices can cause serious ill effects and nausea.

Chronic: Repeated skin contact may cause dermatitis (dry, red skin). Absorption of airborne particles of hormones through the skin may contribute to the effects of exposure as described in "Other Potential Health Effects". Estrogen-progestogen oral contraceptives (such as this product) are known human carcinogens. Norethindrone combined with Ethinyl Estradiol (the active components in this product) is a reproductive toxin.

TARGET ORGANS: *Acute: Industrial Exposure:* Skin. *Therapeutic Doses:* Skin, gastrointestinal system, eyes, central nervous system, genitourinary system, breasts. *Chronic: Industrial Exposure:* Skin. *Therapeutic Doses:* Liver, cardiovascular system, reproductive system, reproductive system, gall bladder, pancreas.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM			
HEALTH HAZARD	(BLUE)		2*
FLAMMABILITY HAZARD	(RED)		1
PHYSICAL HAZARD	(YELLOW)		0
PROTECTIVE EQUIPMENT			
EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8
For Routine Industrial Use and Handling Applications			

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe * = Chronic hazard

11. TOXICOLOGICAL INFORMATION (Continued)

IRRITANCY OF PRODUCT: This product can irritate contaminated tissue.

SENSITIZATION OF PRODUCT: Although rare, some persons may experience allergic reaction to estrogens and experience anaphylactoid/anaphylactic reactions. Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing estrogens and/or progestogens may experience allergic reactions to this product.

TOXICITY DATA: The following are toxicity data for the active components of this product, Ethinyl Estradiol and Norethindrone and the Ferrous Fumarate component of the Placebo pill. This SDS presents human toxicity data, LD₅₀ Oral-Rat and Oral-Mouse data currently available for the active components. Additional data are available for the active components and data are available for other components of this product, but are not presented in this SDS. Contact Allergan for more information.

ETHINYL ESTRADIOL and NORETHINDRONE:

TD (oral, woman) = 138 mg/kg/9 years-intermittent:
Tumorigenic: carcinogenic by RTECS criteria; Liver: tumors

TDLo (oral, woman) = 138 mg/kg/9 years-intermittent:
Tumorigenic: carcinogenic by RTECS criteria; Liver: tumors

TDLo (oral, woman) = 55 mg/kg/5 years-intermittent:
Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting; Nutritional and Gross Metabolic: body temperature increase

TDLo (oral, woman) = 420 µg/kg: female 20 day(s) pre-mating: Reproductive: Maternal Effects: menstrual cycle changes or disorders

TDLo (unreported, woman) = 63,298 µg/kg: female 11-34 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system

TDLo (unreported, woman) = 74,682 µg/kg: female 8-35 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system

ETHINYL ESTRADIOL:

TD (Oral-Woman) 102 mg/kg/5 years-intermittent:
Tumorigenic: carcinogenic by RTECS criteria; Liver: tumors

TDLo (Oral-Woman) 21 mg/kg/21 days-intermittent:
Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting; Nutritional and Gross Metabolic: body temperature increase

TDLo (Oral-Woman) 2738 µg/kg/10 years-intermittent:
Tumorigenic: carcinogenic by RTECS criteria; Liver: angiosarcoma

TDLo (Oral-Woman) 500 µg/kg: female 5 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina; Fertility: other measures of fertility

TDLo (Oral-Woman) 500 µg/kg: female 5 day(s) pre-mating: Reproductive: Maternal Effects: menstrual cycle changes or disorders; Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)

TDLo (Oral-Woman) 160 µg/kg: female 57 week(s) pre-mating: Reproductive: Fertility: other measures of fertility

TDLo (Oral-Woman) 672 µg/kg/96 weeks-intermittent:
Blood: change in clotting factors

ETHINYL ESTRADIOL (continued):

TDLo (Unreported-Woman) 20 µg/kg: female 4 day(s) after conception: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)

TDLo (Unreported-Woman) 500 µg/kg: female 1-5 day(s) after conception: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)

Unscheduled DNA synthesis (Human Mammary Gland) 5 nmol/L

DNA Inhibition (Human Lymphocyte) 50 µmol/L

Cytogenetic Analysis (Human Lymphocyte) 1 mg/L

Sister Chromatid Exchange (Human Lymphocyte) 1 mg/L

DNA Repair (Human Liver) 5 µmol/L/20 hours

NORETHINDRONE:

TDLo (Oral-Woman) 42 mg/kg: Endocrine: androgenic; Skin and Appendages: dermatitis, other (after systemic exposure)

TDLo (Oral-Woman) 4 mg/kg: female 20 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina; Fertility: other measures of fertility

NORETHINDRONE (continued):

TDLo (Oral-Woman) 7143 µg/kg: male 25 day(s) pre-mating: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count), impotence, other effects on male

TDLo (Oral-Woman) 4200 µg/kg: female 21 day(s) pre-mating: Reproductive: Maternal Effects: menstrual cycle changes or disorders; Fertility: other measures of fertility

TDLo (Oral-Woman) 37,800 µg/kg: female 7-24 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system

TDLo (Oral-Woman) 210 µg/kg: female 30 day(s) pre-mating: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated), other measures of fertility

TDLo (Oral-Woman) 28 mg/kg: female 5-25 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system

TDLo (Oral-Woman) 63 mg/kg: female 10-39 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system

NORETHINDRONE (continued):

TDLo (Oral-Woman) 2190 µg/kg: female 52 week(s) pre-mating: Reproductive: Maternal Effects: menstrual cycle changes or disorders

TDLo (Oral-Woman) 7 µg/kg: lactating female 1 day(s) post-birth: Reproductive: Maternal Effects: postpartum

TDLo (Oral-Man) 18 mg/kg: male 42 day(s) pre-mating: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count), testes, epididymis, sperm duct, impotence

TDLo (Oral-Man) 18 mg/kg: male 42 day(s) pre-mating: Reproductive: Paternal Effects: breast development

TDLo (Implant-Woman) 230 µg/kg: female 26 week(s) pre-mating: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)

TDLo (Unreported-Woman) 4200 µg/kg: female 6-8 week(s) after conception: Reproductive: Specific Developmental Abnormalities: musculoskeletal system, urogenital system

NORETHINDRONE (continued):

TDLo (Unreported-Woman) 131 µg/kg: female 52 week(s) pre-mating: Reproductive: Fertility: other measures of fertility

TDLo (Unreported-Woman) 14 mg/kg: female 6-39 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system

TDLo (Unreported-Woman) 12 mg/kg: female 6-20 week(s) after conception: Reproductive: Effects on Newborn: behavioral

TDLo (Unreported-Woman) 76 mg/kg: female 6-32 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system

TDLo (Unreported-Woman) 84 µg/kg: female 12 day(s) pre-mating: Reproductive: Maternal Effects: ovaries, fallopian tubes

LD₅₀ (Oral-Rat) 6 gm/kg

FERROUS FUMARATE:

LDLo (Oral-Woman) 400 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting

LD₅₀ (Oral-Rat) 3850 mg/kg

LD₅₀ (Oral-Mouse) 1570 mg/kg

CARCINOGENIC POTENTIAL: Estrogen-progestogen oral contraceptives (such as this product) are IARC-1 (carcinogenic to Humans) materials. Progestogen-only contraceptives (such as the Norethindrone ingredient in this product) are IARC-2B (Possibly Carcinogenic to Humans) materials. NTP lists Steroidal Estrogens (such as Ethinyl Estradiol) as NTP-K (Known to be Human Carcinogen). NTP lists Norethindrone as NTP-R (Reasonable Anticipated to be Human Carcinogen).

The excipients of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

MAGNESIUM STEARATE (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as Human Carcinogen)

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of this product and its components on the human reproductive system. This product is rated a Pregnancy Risk Category X (CONTRAINDICATED IN PREGNANCY, Fetal risk after drug administration outweighs any health benefit to patient). This product should not be used during pregnancy. The reproductive effects described are related to therapeutic use of this product and are not reported to occur from industrial handling and exposure.

Mutagenicity: Animal mutation data obtained during clinical studies on specific animal tissues exposed to high doses of this compound are available for components of this product as follows: Ethinyl Estradiol.

Embryotoxicity: High doses of the Norethindrone component of this product may cause embryotoxicity.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (Continued):

Teratogenicity: Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb-reduction defects are concerned, when taken inadvertently during early pregnancy.

Reproductive Toxicity: Chronic exposure to this product can cause temporary infertility.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.

ECOTOXICITY: All releases to terrestrial, atmospheric and aquatic environments should be avoided. No specific data is available for this product.

OTHER ADVERSE EFFECTS: This product does not contain any component with known ozone depletion potential.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water. Waste disposal must be in accordance with appropriate International, national, state, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

EUROPEAN WASTE CODES: Wastes from Human or Animal Health Care or Related Research: 18 01 08; Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is NOT classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO): This product is NOT classified as Dangerous Goods, per rules of IMO.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is NOT classified by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES 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 III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

15. REGULATORY INFORMATION (Continued)

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The Ethinyl Estradiol, Norethindrone, and Norethindrone/Ethinyl Estradiol components of this product are on the California Proposition 65 lists. **WARNING!** Contains chemicals known to the state of California to cause cancer and developmental toxicity.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it exempt from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **WARNING!** CANCER HAZARD. CAN CAUSE CANCER. REPRODUCTIVE HAZARD. CONTAINS MATERIAL THAT CAN INJURE UNBORN CHILD. MAY CAUSE SKIN AND EYE IRRITATION. MAY CAUSE ALLERGIC SKIN REACTION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. **FIRST-AID:** In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting. Seek immediate medical attention. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or "alcohol" foam. **IN CASE OF SPILL:** Pick up or sweep up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

COMPONENT GLOBAL HARMONIZATION, EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION FULL TEXT:

Ethinyl Estradiol & Norethindrone:

Signal Word: Danger

Classification: Reproductive Toxicity Cat. 1B, Carcinogenic Cat. 1B, Target Organ Toxicity, repeated exposure, category 1

Hazard Statements: H350 + H360 + H372

Precautionary Statements:

Prevention: P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P281: Use personal protective equipment as needed.

Response: P308 + P313: IF exposed or concerned: Get medical advice/attention.

Storage: P405: Store locked up.

Disposal: P501: Dispose of contents/containers in accordance with all local, regional, national and international regulations.



Hazard Symbol/Pictograms:

ALL OTHER COMPONENTS:

These components do not meet the criteria for classification of hazardous.

COMPONENT EU 67/548/EEC LABELING AND CLASSIFICATION FULL TEXT:

Ethinyl Estradiol & Norethindrone:

Hazard Classification: Toxic.

Risk Phrases: R45, R49, R60, R61, R48

Safety Phrases: [S: 2]: Keep out of the reach of children. [S: 36/37]: Wear suitable protective clothing and gloves. [S: 53]:

Avoid exposure; obtain special instructions before use.



Hazard Symbol:

16. OTHER INFORMATION (Continued)

All Other Components:

Classification: An official classification for these substances has not been published in Commission Directives.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

This Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Allergan's knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

REVISION DETAILS: Updated with GHS information and added internal exposure limit

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc.

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