

# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Norgestimate and Ethinyl Estradiol Tablets, USP
<b>Synonyms:</b>	18,19-Dinor-17-pregn-4-en-20-yn-3-one,17-(acetyloxy)-13-ethyl-, oxime, (17alpha)-(+)-;19-Norpregna-1,3,5(10)-trien-20-yne-3,17-diol, (17alpha)-
<b>National Drug Code (NDC):</b>	17478-260-06 17478-260-28 17478-261-06 17478-261-28
<b>Recommended Use:</b>	Pharmaceutical. Norgestimate and Ethinyl Estradiol Tablets, USP are indicated for use by females of reproductive potential to prevent pregnancy and treatment of moderate acne vulgaris in females at least 15 years of age.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classifiable.
<b>Health Hazards:</b>	Not classifiable.
<b>Symbol(s):</b>	None.
<b>Signal Word:</b>	None.
<b>Hazard Statement(s):</b>	None.
<b>Precautionary Statement(s):</b>	None.
<b>Hazards Not Otherwise Classified:</b>	None.
<b>Supplementary Information:</b>	None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Each Tablet Contains
Norgestimate	18,19-Dinor-17-pregn-4-en-20-yn-3-one, 17-(acetyloxy)-13-ethyl-, oxime, (17alpha)-(+)-	35189-28-7	C <sub>23</sub> H <sub>31</sub> NO <sub>3</sub>	369.51	0.25 mg; 0.18 mg or 0.215 mg
Ethinyl Estradiol	19-Norpregna-1,3,5(10)-trien-20-yne-3,17-diol, (17alpha)-	57-63-6	C <sub>20</sub> H <sub>24</sub> O <sub>2</sub>	296.4	0.035 mg

The formula also contains Colloidal Silicone Dioxide, FD&C Blue No.2 Aluminum Lake, Lactose, Magnesium Stearate and Pregelatinized Corn Starch.

# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

### 4. FIRST AID MEASURES

<b>Ingestion:</b>	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	None known from workplace exposure. In clinical use, the most common adverse reactions were: headache/migraine, abdominal/gastrointestinal pain, vaginal infections, genital discharge, breast issues (including breast pain, discharge, and enlargement), mood disorders (including mood alteration and depression), flatulence, nervousness, rash, changes in weight (including weight increased or decreased).
<b>Medical Conditions Aggravated by Exposure:</b>	No data available.

# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

### Notes to Physician:

Treat supportively and symptomatically. Do not prescribe Norgestimate and Ethinyl Estradiol Tablets, USP to women who are known to have the following conditions:

- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
  - Smoke, if over age 35
  - Have deep vein thrombosis or pulmonary embolism, now or in the past
  - Have inherited or acquired hypercoagulopathies
  - Have cerebrovascular disease
  - Have coronary artery disease
  - Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
  - Have uncontrolled hypertension
  - Have diabetes mellitus with vascular disease
  - Have headaches with focal neurological symptoms or migraine headaches with aura
- Women over age 35 with any migraine headaches
- Liver tumors, benign or malignant, or liver disease
- Undiagnosed abnormal uterine bleeding
- Pregnancy, because there is no reason to use COCs during pregnancy
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past

### 5. FIREFIGHTING MEASURES

**Suitable Extinguishing Media:** Use water, carbon dioxide, dry chemical or water spray.

**Unsuitable Extinguishing Media:** Not determined.

#### Specific Hazards Arising from the Chemical

**Hazardous Combustion Products:** No data available.

**Other Specific Hazards:** No data available.

**Special Protective Equipment and Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) Protect from light.

**Specific End Use:** Pharmaceutical drug product.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Occupational Exposure Guidelines:**

Ingredient	Type	Value
Norgestimate	No data available	No data available
Ethinyl Estradiol	TWA	0.2 mcg/m <sup>3</sup>
Ethinyl Estradiol	OEL TLV	0.0001 mg/m <sup>3</sup>

*TWA: Time Weighted Average; OEL: Occupational Exposure Limit; TLV: Threshold Limit Value*

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Eyes Protection:** Not required for normal use. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

<b>Hand Protection:</b>	Not required for normal use. Chemically compatible gloves are recommended for bulk handling. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Skin Protection:</b>	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
<b>General Hygiene Considerations:</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State/Color:</b>	<p>Norgestimate and Ethinyl Estradiol Tablets, USP 0.25 mg/0.035 mg are available in a blister card: (NDC 17478-260-28). Each blister card contains 28 tablets:</p> <ul style="list-style-type: none"><li>• 21 dark blue unscored round tablets debossed with on one side with "14"; the tablet contains 0.25 mg Norgestimate and 0.035 mg Ethinyl estradiol</li><li>• 7 white round unscored tablets (non-hormonal placebo) debossed on one side with "11"; the tablet contains inert ingredients</li></ul> <p>Norgestimate and Ethinyl Estradiol Tablets, USP 0.18 mg/0.035 mg, 0.215 mg/0.035 mg and 0.25 mg/0.035 mg are available in a blister card: (NDC 17478-261-28). Each blister card contains 28 tablets:</p> <ul style="list-style-type: none"><li>• 7 light blue unscored round tablets debossed on one side with "12"; the tablet contains 0.18 mg Norgestimate and 0.035 mg Ethinyl estradiol</li><li>• 7 medium blue unscored round tablets debossed on one side with "13"; the tablet contains 0.215 mg Norgestimate and 0.035 mg Ethinyl estradiol</li><li>• 7 dark blue unscored round tablets debossed on one side with "14"; the tablet contains 0.25 mg Norgestimate and 0.035 mg Ethinyl estradiol and</li><li>• 7 white round unscored tablets (non-hormonal placebo) debossed on one side with "11"; the tablet contains inert ingredients</li></ul>
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.

# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	No data available.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	Not determined.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Not determined.
<b>Incompatible Materials:</b>	Strong oxidizing agents.
<b>Hazardous Decomposition Products:</b>	Not determined.

### 11. TOXICOLOGICAL INFORMATION

#### Information on the Likely Routes of Exposure

<b>Inhalation:</b>	No data available.
<b>Ingestion:</b>	No data available.
<b>Skin Contact:</b>	No data available.
<b>Eye Contact:</b>	No data available.

#### **Symptoms Related to the Physical, Chemical and Toxicological Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

#### **Delayed and Immediate Effects of Exposure:**

No data available.

# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Norgestimate	Rat	Oral	LD <sub>50</sub>	1,000 mg/kg
Ethinyl Estradiol	Rat	Oral	LD <sub>50</sub>	960 mg/kg

### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

### Repeated Does Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

**Aspiration Hazard:** No data available.  
**Toxicokinetics/Metabolism:** No data available.  
**Target Organ Effects:** No data available.  
**Systemic Effects:** No data available.

**Reproductive Effects:** Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptive prior to pregnancy.

**Carcinogenicity:** Norgestimate and Ethinyl Estradiol Tablets, USP are contraindicated in women who currently have or have had breast cancer because breast cancer may be hormonally sensitive.

There is substantial evidence that combination oral contraceptive (COC) do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings.

# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

Some studies suggest that COC use has been associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.

**National Toxicology Program (NTP):** Ethinyl Estradiol - known to be carcinogenic to humans.  
Norgestimate - suspect of causing cancer.

**International Agency for Research on Cancer (IARC):** Ethinyl Estradiol - known to be carcinogenic to humans.  
Norgestimate - suspect of causing cancer.

**Occupational Safety and Health Administration (OSHA):** Not Regulated.

### 12. ECOLOGICAL INFORMATION

#### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Norgestimate	No data available	No data available	No data available	No data available
Ethinyl Estradiol	Daphnia magna	EC <sub>50</sub>	5.7 mg/l	48 hours
Ethinyl Estradiol	Oncorhynchus mykiss (reported as Salmo gairdneri)	LC <sub>50</sub>	1.6 mg/l	96 hours

**Terrestrial Toxicity:** No data available.  
**Persistence and Degradability:** No data available.  
**Bioaccumulative Potential:** No data available.  
**Mobility in Soil:** No data available.  
**Mobility in Environment:** No data available.  
**Other Adverse Effects:** No data available.

### 13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. TRANSPORT INFORMATION

**Department of Transportation (DOT):** Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable



# SAFETY DATA SHEET

## Norgestimate and Ethinyl Estradiol Tablets, USP

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

### 15. REGULATORY INFORMATION

#### US FEDERAL REGULATIONS

**Toxic Substance Control Act (TSCA):**

Ingredient	Inventory
Norgestimate	No
Ethinyl Estradiol	Yes

**CERCLA Hazardous Substance:**

Ingredient	Reportable Quantity
Not applicable	Not applicable

**EPCRA Extremely Hazardous Substances and Toxic Chemicals:**

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

#### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Norgestimate	Listed	Listed	Not listed
Ethinyl Estradiol	Listed	Listed	Listed

**California Proposition 65:**

Ethinyl Estradiol is known to State of California to cause cancer, birth defects, or other reproductive harm.

### 16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

**Disclaimer:** This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.