Oxiconazole nitrate is a nitrate of the imidazole derivative oxiconazole, used in topical dermatological conditions, especially for treating infections caused by certain fungi, such as tinea corporis, tinea cruris, tinea pedis, and tinea (pityriasis) versicolor. It is also used for treating infections caused by Candida albicans, Microsporum canis, and Trichophyton mentagrophytes. Oxiconazole nitrate is thought to work by inhibiting the growth of fungal cells through its antifungal activity.

**Pharmacokinetics:**
- Absorption: Oxiconazole nitrate is well absorbed from the skin, with peak plasma concentrations achieved within 2 to 4 hours after application.
- Distribution: The drug is distributed in the skin and subcutaneous tissues, with concentrations in the epidermis being higher than in the dermis.
- Metabolism: Oxiconazole nitrate is metabolized in the liver, with metabolites excreted in the urine.
- Elimination: The drug is eliminated mainly through the urine, with a half-life of approximately 3 hours.

**Contraindications:**
- Patients with a history of sensitivity to oxiconazole nitrate or any ingredient of the formulation.
- Patients with known hypersensitivity to imidazole derivatives.

**Warnings:**
- Pregnancy: Oxiconazole nitrate is classified as Pregnancy Category B.
- Breastfeeding: It is not known whether oxiconazole nitrate is excreted in human milk. When nursing women use OXISTAT® Cream or Lotion, they should avoid nursing during and for at least 24 hours after application.

**Precautions:**
- Use OXISTAT® Cream or Lotion as directed by the physician.
- Avoid use in the eyes, mouth, and anus.
- Avoid use in the periorificial skin and mucous membranes.
- Use the medication for 2 weeks or until all symptoms are improved.

**Adverse Reactions:**
- The most common adverse reactions associated with the use of oxiconazole nitrate cream include dermatitis, eczema, and contact dermatitis.
- Other possible adverse reactions include irritation, burning, and itching.

**Drug Interactions:**
- No significant drug interactions have been reported with oxiconazole nitrate.

**Special Populations:**
- Elderly: Oxiconazole nitrate is excreted in the urine, and elderly patients may have reduced renal function, so dosing adjustments may be necessary.

**Dosage and Administration:**
- Apply OXISTAT® Cream or Lotion to the affected area and cover with a protective dressing, if necessary.
- Apply the medication twice daily for 2 weeks or until all symptoms are improved.

**Description:**
- OXISTAT® Cream and Lotion are for external dermal use only. Avoid introduction of OXISTAT® Cream or Lotion ophthalmic or intravaginal use.
- OXISTAT® Cream is supplied in 30-g tubes (NDC 0462-0358-30) and 60-g tubes (NDC 0462-0358-60).

**Pharmacology:**
- Oxiconazole nitrate is an imidazole derivative whose antifungal activity is derived primarily from its ability to inhibit fungal cell growth. It is a potent inhibitor of cytochrome P-450-dependent oxidases, which are involved in the metabolism of certain endogenous compounds, including vitamin D3.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:**
- There are no data on the carcinogenic potential of oxiconazole nitrate in animals or in humans.

**Pediatric Use:**
- In children, oxiconazole nitrate is not recommended for use in children younger than 12 years of age.

**Clinical Trials:**
- In two controlled clinical trials, OXISTAT® Cream was compared to a placebo in the treatment of tinea (pityriasis) versicolor. The results of these trials showed that OXISTAT® Cream was superior to placebo in terms of clinical improvement and mycological cure.

**Teratogenic Effects:**
- Oxiconazole nitrate has not been assessed for teratogenic potential in preclinical studies.

**Animal Reproduction Studies:**
- Oxiconazole nitrate was administered to rats, rabbits, and mice at oral doses up to 100, 150, and 200 mg/kg/day (57, 40, and 27 times the human dose based on mg/m2), respectively. There were no effects on fertility, reproduction, or development of the offspring.

**Pregnancy Category:**
- Pregnancy Category B.

**Nursing Mothers:**
- It is not known whether oxiconazole nitrate is excreted in human milk. When nursing women use OXISTAT® Cream or Lotion, they should avoid nursing during and for at least 24 hours after application.

**Clinical Pharmacology:**
- Oxiconazole nitrate is a nitrate of the imidazole derivative oxiconazole, used in topical dermatological conditions, especially for treating infections caused by certain fungi, such as tinea corporis, tinea cruris, tinea pedis, and tinea (pityriasis) versicolor. It is also used for treating infections caused by Candida albicans, Microsporum canis, and Trichophyton mentagrophytes. Oxiconazole nitrate is thought to work by inhibiting the growth of fungal cells through its antifungal activity.