Safety Data Sheet
ANASTRAZOLE TABLETS

Strength: 1mg. **Pack Size:** Bottles of 30 Tablets / 1000 Tablets **Revision No.:** 02

EMERGENCY OVERVIEW

Each Anastrazolel Tablet intended for oral administration contains Anastrazole and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

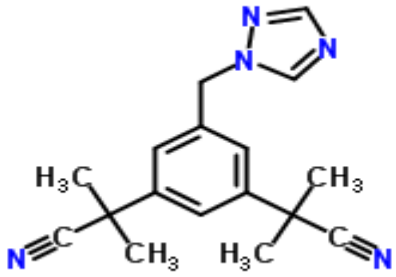
Section 1. Identification

Identification of the product

Product name: Anastrazole Tablets

Formula: $C_{17}H_{19}N_5$

Chemical Name: 1 ,3-Benzenediacetonitrile, a, a, a', a'-tetramethyl-5-(I H-1 ,2,4-triazol-1-ylmethyl)



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

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Recommended use / Therapeutic Category Non-steroidal aromatase inhibitor

Restriction on Use / Contraindications:

Pregnancy and Premenopausal Women:

Anastrozole tablets may cause fetal harm when administered to a pregnant woman and offers no clinical benefit to premenopausal women with breast cancer. Anastrozole tablets are contraindicated in women who are or may become

pregnant. There are no adequate and well-controlled studies in pregnant women using anastrozole tablets. If anastrozole tablets are used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus or potential risk for loss of the pregnancy.

Hypersensitivity:
Anastrozole tablets are contraindicated in any patient who has shown a hypersensitivity reaction to the drug or to any of the excipients. Observed reactions include anaphylaxis, angioedema, and urticaria.

Section 2. Hazard (s) Identification

Dose and Administration

The dose of anastrozole tablet is one 1 mg tablet taken once a day. For patients with advanced breast cancer, Anastrozole tablet should be continued until tumor progression. Anastrozole tablets can be taken with or without food.

Adverse Effects

Serious adverse reactions with anastrozole tablets occurring in less than 1 in 10,000 patients, are: 1) skin reactions such as lesions, ulcers, or blisters; 2) allergic reactions with swelling of the face, lips, tongue, and/or throat. This may cause difficulty in swallowing and/or breathing; and 3) changes in blood tests of the liver function, including inflammation of the liver with symptoms that may include a general feeling of not being well, with or without jaundice,liver pain or liver swalling. Common adverse reactions (occurring with an incidence of >10%) in women taking anastrozole tablets included: hot flashes, asthenia, arthritis, pain, arthralgia, pharyngitis, hypertension, depression, nausea and vomiting, rash, osteoporosis, fractures, back pain, insomnia, pain, headache, bone pain, peripheral edema, increased cough, dyspnea, pharyngitis and lymphedem

Over Dose Effect

Clinical trials have been conducted with anastrozole tablets, up to 60 mg in a single dose given to healthy male volunteers and up to 10 mg daily given to postmenopausal women with advanced breast cancer; these dosages were tolerated. A single dose of anastrozole tablets that results in life-threatening symptoms has not been established. There is no specific antidote to over dosage and treatment must be symptomatic.

Medical Condition

Hepatic Impairment:
No changes in dose are recommended for patients with mild-to-moderate hepatic impairment. Anastrozole tablet has not been

	studied in patients with severe hepatic impairment
Contraindications	**Pregnancy and Premenopausal Women:** Anastrozole tablets may cause fetal harm when administered to a pregnant woman and offers no clinical benefit to premenopausal women with breast cancer. Anastrozole tablets are contraindicated in women who are or may become pregnant. There are no adequate and well-controlled studies in pregnant women using anastrozole tablets. If anastrozole tablets are used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus or potential risk for loss of the pregnancy. **Hypersensitivity:** Anastrozole tablets are contraindicated in any patient who has shown a hypersensitivity reaction to the drug or to any of the excipients. Observed reactions include anaphylaxis, angioedema, and urticaria.
Pregnancy Comments	**Teratogenic Effects :** Anastrozole tablets may cause fetal harm when administered to a pregnant woman and offers no clinical benefit to premenopausal women with breast cancer. Anastrozole tablets is contraindicated in women who are or may become pregnant. In animal studies, anastrozole caused pregnancy failure, increased pregnancy loss, and signs of delayed fetal development. There are no studies of anastrozole tablets use in pregnant women. If anastrozole tablet is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus and potential risk for pregnancy loss. **Nursing Mothers:** It is not known if anastrozole is excreted in human milk. Because many drugs are excreted in human milk and because of the tumorigenicity shown for anastrozole in animal studies, or the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother
Pregnancy Category	X

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Anastrozol 1mg	Not Found	120511-73-1
Inactive Ingredients :		
Lactose	Not Found	63-42-3
Megnesium Stearate,	Not Found	557-04-0
Hyaroxypropyl methyl cellulose,	Not Found	9004-65-3
Polyethylene glycol,	Not Found	25322-68-3
Povidone.	Not Found	9003-39-8
Sodium starch glycolate	Not Found	NA
Titanium dioxide	Not Found	13463-67-7

Section 4. First - aid measures

General Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity reaction must receive medical attention.

Overdose Treatment In the management of an overdose, consider that multiple agents may have been taken. Vomiting may be induced if the patient is alert. Dialysis may be helpful because anastrozole tablet is not highly protein bound. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is indicated.

Section 5. Fire - fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	Emits toxic fumes Under fire conditions.

Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage	Store at 20° to 25°C (68° to 77°F)**.** Controlled Room Temperature.
Incompatibilities:	No data available

Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Engineering Control	Use process enclosures, local exhauste ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Section 9. Physical and chemical properties

Appearance	Anastrazole Tablets 1 mg are white, biconvex, round coated tablets, debossed with ‘A 7’ on one side and plain on other side.	**Odour**	Odourless
Solubility in water	No Data Available	**Melting Point**	No Data Available
Boiling point	No Data Available	**Vapour density**	No Data Available

Evaporation rate	No Data Available	**Evaporation rate**	No Data Available
Reactivity in water	No Data Available	**Specific gravity**	No Data Available
% Volatile by volume	No Data Available	**Vapour pressure**	No Data Available
Other information	No Data Available		

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities:	No Data Available		

Section 11. Toxicology information

General

Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ

Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Other

Reproductive Toxicology
Anastrozole has been found to cross the placenta following oral administration of 0.1 mg/kg in rats and rabbits (about 1 and 1.9 times the recommended human dose, respectively, on a mg/m^2 basis). Studies in both rats and rabbits at doses equal to or greater than 0.1 and 0.02 mg/kg/day, respectively (about 1 and 1/3, respectively, the recommended human dose on a mg/m^2 basis), administered during the period of organogenesis showed that anastrozole increased pregnancy loss (increased pre- and/or post-implantation loss, increased resorption, and decreased numbers of live fetuses); effects were dose related in rats. Placental weights were significantly increased in rats at doses of 0.1 mg/kg/day or more.

Evidence of fetotoxicity, including delayed fetal development (i.e., incomplete ossification and depressed fetal body weights), was observed in rats administered doses of 1 mg/kg/day (which produced plasma anastrozole C_{ssmax} and $AUC_{0\text{-}24\ hr}$ that were 19 times and 9 times higher than the respective values found in postmenopausal volunteers at the recommended dose). There was no evidence of teratogenicity in rats administered doses up to 1.0 mg/kg/day. In rabbits, anastrozole caused pregnancy failure at doses

equal to or greater than 1.0 mg/kg/day (about 16 times the recommended human dose on a mg/m^2 basis); there was no evidence of teratogenicity in rabbits administered 0.2 mg/kg/day (about 3 times the recommended human dose on a mg/m^2 basis).

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Disposal Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea(IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 078921

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.