

# Material Safety Data Sheet

## Bicalutamide Tablets

Strength: 50 mg.

Pack Size: 30,100,500, 1000 Tablets per bottle

Strength: 50 mg.

Pack Size: blister pack of 100 tablets

Strength: 50 mg.

Pack Size: in unit-of-use package of 30 tablets

Revision No.: 00

### EMERGENCY OVERVIEW

BICALUTAMIDE TABLETS contain Bicalutamide and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

## Section 1. Identification of the substance

### Identification of the product

Product name:	BICALUTAMIDE TABLETS
Chemical Formula:	$C_{18}H_{14}N_2O_4F_4S$
Chemical Name:	The chemical name is propanamide, N [4 cyano-3(trifluoromethyl)phenyl]-3-[(4-fluorophenyl)sulfonyl]-2hydroxy- 2-methyl-,(++)
Therapeutic Category	Bicalutamide is a androgen receptor inhibitor

### Manufacturer / supplier identification

Company:	Cadila Healthcare Ltd. Ahmedabad, India
Contact for information:	Tel.: +91 2717 250337 Fax: +91 2717 250319
Emergency telephone No.	Tel.: +91 2717 250331, 250332, 250336

## Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
<b>Principle Component :</b>		
Bicalutamide	Not Found	90357-06-5
<b>Inactive Ingredients :</b>		
Lactose monohydrate	Not Found	67392-87-4
Sodium starch glycolate	Not Found	9063-38-1
Povidone	Not Found	9003-39-8
Magnesium stearate	Not Found	557-04-0

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### Section 3. Health Hazards Information

#### Dose and Administration

The recommended dose for bicalutamide therapy in combination with an LHRH analog is one 50 mg tablet once daily (morning or evening), with or without food. It is recommended that bicalutamide be taken at the same time each day. Treatment with bicalutamide should be started at the same time as treatment with an LHRH analog.

#### Adverse Effects

Adverse reactions that occurred in more than 10% of patients receiving bicalutamide plus an LHRH-A were: hot flashes, pain (including general, back, pelvic and abdominal), asthenia, constipation, infection, nausea, peripheral edema, dyspnea, diarrhea, hematuria, nocturia and anemia.

#### Body as a Whole:

Neoplasm; Neck Pain; Fever; Chills; Sepsis; Hernia; Cyst

#### Cardiovascular:

Angina Pectoris; Congestive Heart Failure; Myocardial Infarct; Heart Arrest; Coronary Artery Disorder; Syncope

#### Digestive:

Melena; Rectal Hemorrhage; Dry Mouth; Dysphagia; Gastrointestinal Disorder; Periodontal Abscess; Gastrointestinal Carcinoma

#### Metabolic and Nutritional:

Edema; BUN Increased; Creatinine Increased; Dehydration; Gout; Hypercholesteremia

#### Musculoskeletal:

Myalgia; Leg Cramps

#### Nervous:

Hypertonia; Confusion; Somnolence; Libido Decreased; Neuropathy; Nervousness

#### Respiratory:

Lung Disorder; Asthma; Epistaxis; Sinusitis

#### Skin and Appendages:

Dry Skin; Alopecia; Pruritus; Herpes Zoster; Skin Carcinoma; Skin Disorder

#### Special Senses:

Cataract specified

#### Urogenital:

Dysuria; Urinary Urgency; Hydronephrosis; Urinary Tract Disorder

**Abnormal Laboratory Test Values :** Laboratory abnormalities including elevated AST, ALT, bilirubin, BUN, and creatinine and decreased hemoglobin and white cell count have been reported in both bicalutamide-LHRH analog treated and flutamide-LHRH analog treated patients.

#### Over Dose Effect

Long-term clinical trials have been conducted with dosages up to 200 mg of bicalutamide daily and these dosages have been well tolerated. A single dose of bicalutamide that results in symptoms of an overdose considered to be life threatening has not been established.

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### Contraindications **Hypersensitivity**

Bicalutamide is contraindicated in any patient who has shown a hypersensitivity reaction to the drug or any of the tablet's components. Hypersensitivity reactions including angioneurotic edema and urticaria have been reported .

### Women

Bicalutamide has no indication for women, and should not be used in this population.

### Pregnancy

Bicalutamide may cause fetal harm when administered to a pregnant woman. Bicalutamide is contraindicated in women, including those who are or may become pregnant.

### Pregnancy Comments

Bicalutamide may cause fetal harm when administered to a pregnant woman. Bicalutamide is contraindicated in women, including those who are or may become pregnant. There are no studies in pregnant women using bicalutamide. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be appraised of the potential hazard to the fetus.

### Pregnancy Category

X

## Section 4. First aid measures

### General

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

### Overdose Treatment

There is no specific antidote; treatment of an overdose should be symptomatic.

In the management of an overdose with bicalutamide, vomiting may be induced if the patient is alert. It should be remembered that, in this patient population, multiple drugs may have been taken. Dialysis is not likely to be helpful since bicalutamide is highly protein bound and is extensively metabolized. 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

This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.

### Fire Fighting Procedure

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

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### Section 6. Storage / Spill / Disposal Measures

Storage	Store at 20° to 25°C (68° to 77°F). Dispense in a tight container.
Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage using high efficiency vacuum cleaner. Avoid breathing dust.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

### Section 7. Exposure controls and 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.

### Section 8. Physical and chemical properties

<b>Appearance</b>	Bicalutamide Tablets, 50 mg are white to off-white, round, biconvex, film-coated tablets, imprinted with "ZE 57" in black ink on one side and plain on other side		
<b>Solubility/ water</b>	No Data Available	<b>Odour</b>	Odourless
<b>Boiling point</b>	No Data Available	<b>Melting Point</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>Percentage Volatile by volume</b>	No Data Available	<b>Specific gravity</b>	No Data Available
<b>Vapour pressure</b>	No Data Available		
<b>Other information</b>	Bicalutamide has a molecular weight of 430.37. Bicalutamide is a white to off-white powder which is practically insoluble in water at 37°C (5 mg per 1000 mL), slightly soluble in chloroform and absolute ethanol, sparingly soluble in methanol, and soluble in acetone and tetrahydrofuran.		

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### Section 9. Physical Hazards

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

### Section 10. Toxicological 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	<p>In male rats dosed at 250 mg/kg/day (approximately 2 times human therapeutic concentrations<sup>*</sup>), the pre-coital interval and time to successful mating were increased in the first pairing but no effects on fertility following successful mating were seen. These effects were reversed by 7 weeks after the end of an 11-week period of dosing.</p> <p>No effects on female rats dosed at 10, 50 and 250 mg/kg/day (approximately 2/3, 1 and 2 times human therapeutic concentrations, respectively<sup>*</sup>) or their female offspring were observed. Administration of bicalutamide to pregnant females resulted in feminization of the male offspring leading to hypospadias at all dose levels. Affected male offspring were also impotent.</p>

### Section 11. Ecological information

No data available on Ecotoxicity

### Section 12. Other information

None

Date of issue: 19/03/2009

Supersedes edition of: New Edition

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.