

**Anastrozole Cas No. : 120511-73-1**

Doctors take into account many different factors when planning each person's treatment, so it is important to talk things over with your specialist. They will make a decision about treatment based on current medical knowledge and your individual situation.

Active Pharmaceuticals Ingredients Manufacturers

**Taj Pharmaceuticals Ltd.****Anastrozole****CAS No. : 120511-73-1****Anastrozole [USAN:BAN:INN]****Anastrozole (JAN/USP)**

CAS Number:120511-73-1

Molecular Formula:C17H19N5

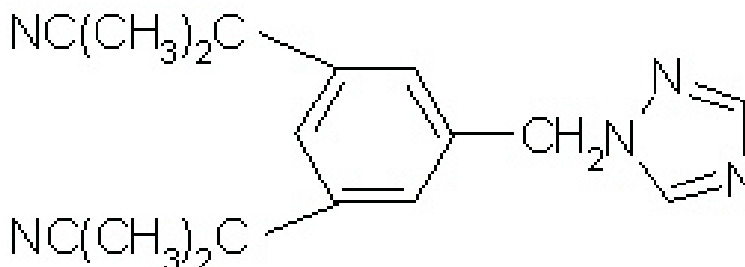
Molecular Weight:293.37

Density:1.08 g/cm<sup>3</sup>

Melting Point:81-82 °C

Boiling Point:469.7 °C at 760 mmHg

Flash Point:237.9 °C

Appearance:White or off-white crystalline powder  
120511-73-1 (ANASTROZOLE)**Therapeutic category: Anti-cancer**

Appearance: White or off-white crystalline powder

Purity: 99%min

**Specification:**

Characteristics: White crystalline powder

Solubility: Very soluble in acetonitrile, freely soluble in water, methanol

Melting point: 82~83°

Identification: IR spectrum

**Related substances**

Any single impurities =0.5%, Total impurities =1.0%

Loss on drying(%): 0.23%, Sulphated ash(%): 0.05%

Heavy Metals =0.001%, Assay(HPLC): 99.1%

Microbiological Items, Total Plate Count: 1000 cfu/g

Yeast &amp; Mold: 100 cfu/g

E. coli: Negative

Salmonella: Negative

1,3-Benzenediacetonitrile,R,R,R',R'-tetramethyl- 5-(1H-1,2,4-triazol-1-ylmethyl)-

alpha,alpha,alpha,alpha-Tetramethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-m-benzenediacetonitrile

Anastrozole

Altrol® (Anastrozole 1mg Tablets) (Registered trademark for Taj Pharmaceuticals Limited.)

PRODUCT FOR BREAST CANCER (HIGHLY RECOMMENDED BY DOCTORS WORLDWIDE)

ICI-D 1033

1,3-Benzenediacetonitrile, alpha,alpha,alpha,alpha-tetramethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-

ZD 1033

**USES**

Doctors take into account many different factors when planning each person's treatment, so it is important to talk things over with your specialist. They will make a decision about treatment based on current medical knowledge and your individual situation.



Taj Pharmaceuticals Ltd.  
**Anastrozole**

CAS NO- 120511-73-1

### Early breast cancer

ANASTROZOLE can be used to treat post-menopausal women with early breast cancer (cancer that has not spread) after they have had surgery to remove the cancer. Giving treatment after surgery is known as adjuvant therapy.

Results from recent research studies suggest that for some women ANASTROZOLE may be more effective than tamoxifen, and that it has different side effects. It has also been shown that switching to ANASTROZOLE after taking tamoxifen for 2–3 years may be better than five years of tamoxifen for some women.

The National Institute for Health and Clinical Excellence (NICE) advise doctors on the prevention and treatment of ill-health, and have produced guidance on the use of aromatase inhibitors in early breast cancer. The guidelines currently recommend that an aromatase inhibitor, such as ANASTROZOLE, should be considered as an adjuvant treatment for all women with early breast cancer. The choice about which hormonal therapy to use should be made following discussion between the doctor and the patient, and should include information about the potential risks and benefits of the treatment.

### Advanced breast cancer

ANASTROZOLE can also be used to treat women who have breast cancer that has spread to other parts of the body (advanced breast cancer) or breast cancer that has come back after initial treatment.

### HOW TO USE

The dose of ANASTROZOLE is one 1 mg tablet taken once a day. For patients with advanced breast cancer, ANASTROZOLE should be continued until tumor progression.

For adjuvant treatment of early breast cancer in postmenopausal women, the optimal duration of therapy is unknown. In the ATAC trial ANASTROZOLE was administered for five years.

**Patients with Hepatic Impairment:** Hepatic metabolism accounts for approximately 85% of anastrozole elimination. Although clearance of anastrozole was decreased in patients with cirrhosis due to alcohol abuse, plasma anastrozole concentrations stayed in the usual range seen in patients without liver disease. Therefore, no changes in dose are recommended for patients with mild-to-moderate hepatic impairment, although patients should be monitored for side effects. ANASTROZOLE has not been studied in patients with severe hepatic impairment.

**Patients with Renal Impairment:** No changes in dose are necessary for patients with renal impairment.

**Use in the Elderly:** No dosage adjustment is necessary.

### SIDE EFFECTS

Each person's reaction to any medication is different. Most people have very few side effects with ANASTROZOLE, while others may experience more. The side effects described in this factsheet will not affect everyone and may be different if you are taking more than one drug.

We have outlined the most common side effects. However, we have not included those that are very rare and therefore extremely unlikely to affect you. If you notice any effects that are not listed in this information, please discuss them with your doctor or nurse.

You will see your doctor regularly while you have this treatment so that they can monitor the effects. This information should help you to discuss any queries about your treatment and its side effects with your doctor or nurse, as they are in the best position to help and advise you.

Some people may have the following side effects to varying degrees:

**Hot flushes and sweats** These are usually mild and may wear off after a period of time. Sometimes women find that avoiding or cutting down on tea, coffee, nicotine and alcohol can reduce sweats. Recent research suggests that progestogen or some anti-depressants may be helpful in controlling this side effect. Your doctor or nurse can discuss this with you.



Some women find that complementary therapies help, and your GP may be able to give you details about getting these on the NHS.

If you are having troublesome hot flushes, discuss these with your doctor.

**Vaginal dryness** This may occur while using ANASTROZOLE. Gels that can help to overcome the dryness are available. The gels can be bought from any chemist or can be prescribed by your doctor.

**Feeling sick (nausea), being sick (vomiting) and diarrhoea** These side effects are rare. If they occur they can usually be effectively treated, so let your doctor know. Feeling sick can often be relieved by taking your tablet with food or at night. If you have diarrhoea it is important to drink plenty of fluids.

**Hair thinning** Some women notice that their hair becomes thinner while taking ANASTROZOLE. This is usually mild and the hair regrows at the end of treatment.

**Headaches** Some people have headaches whilst taking ANASTROZOLE but this is not common. It is important to drink plenty of fluids. Let your doctor know if you are getting headaches, as they can prescribe medication.

**Skin rashes** Rarely, ANASTROZOLE can cause skin rashes.

**Vaginal bleeding** Vaginal bleeding (usually in the first few weeks of treatment) has been reported. This is rare and has usually occurred after changing from other hormonal therapies to treatment with ANASTROZOLE. If the bleeding continues, tell your doctor or breast-care nurse.

**Joint pains/muscular stiffness** Some women have pain and stiffness in their joints while taking ANASTROZOLE. Let your doctor know if these effects are troublesome. It may be helpful to take mild painkillers.

**Tiredness and lethargy** Some people can have increased tiredness, especially at the start of treatment. It is important to get plenty of rest. If you are very sleepy you should take extra care when driving or operating machinery.

**Risk of osteoporosis** Women who have osteoporosis (weakened bones) or are at risk of it, should have their bone strength assessed before and during treatment with ANASTROZOLE. In some situations it may be necessary to start treatment to help prevent osteoporosis from developing.

**Note /Government Notification:** These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

**Information:** The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers. Also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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