Applicant : Eurolab (Pty) Ltd
Proprietary name : Stradexa
Dosage form and strength : Film-coated tablet 1 mg
Date of submission : 07 April 2021
Approval date : 07 May 2021

**APPROVED PROFESSIONAL INFORMATION**

**SCHEDULING STATUS** **S4**

## 1 NAME OF THE MEDICINE

Stradexa 1 mg Film-Coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Stradexa tablets for oral administration contain 1 mg of Anastrozole.

Each tablet contains 95,25 mg lactose.

For full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-Coated Tablets

White to off white, round, biconvex, film coated tablets with 'AHI' debossing on one side and plain on the other side.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

- Treatment of early breast cancer in postmenopausal women. Treatment of advanced breast cancer in postmenopausal women.
- Efficacy has not been demonstrated in oestrogen receptor negative patients unless they have had a previous positive clinical response to tamoxifen.

### 4.2 Posology and method of administration

The dose of Stradexa is 1 mg tablet taken once a day.

Renal impairment: no dose adjustment required in patients with mild or moderate impairment.

Hepatic impairment: no dose adjustment with mild hepatic impairment.

### 4.3 Contraindications

- Stradexa is contra-indicated in any patient who has shown a hypersensitivity reaction to anastrozole or to any of the excipients.

- Pre-menopausal women
- Patients with severe renal impairment (creatinine clearance less than 20 ml/min)
- Pregnant and lactating women
- Patients with moderate or severe hepatic disease

**4.4 Special warnings and precautions for use**

As Stradexa lowers circulating oestrogen levels it may cause a reduction in bone mineral density with a consequent increased risk of fracture.

Stradexa is not recommended for use in children and is contra-indicated in pre-menopausal women as safety and efficacy has not been established in these groups of patients. The menopause should be defined biochemically in any patient where there is doubt about hormonal status. There is no data to support the safe use of Stradexa in patients with moderate or severe hepatic impairment, or patients with severe impairment of renal function (creatinine clearance less than 20 ml/min).

**4.5 Interaction with other medicines and other forms of interaction**

- Antipyrine and cimetidine clinical interaction studies indicate that co-administration of Stradexa with other medicines is unlikely to result in clinically significant interactions mediated by cytochrome P450.
- Tamoxifen and/or oestrogen containing therapies should not be co-administered with Stradexa as it would diminish its pharmacological action.

**4.6 Fertility, pregnancy and lactation**

Stradexa is contra-indicated in pregnant and lactating women.

**4.7 Effects on ability to drive and use machines**

Asthaenia, somnolence and dizziness have been reported with the use of Stradexa and caution should be observed when driving or operating machinery while such symptoms persist. Special precautions should be taken for patients that are lactose intolerant.

**4.8 Undesirable effects**

| System Organ Class | Frequencies | Adverse Reaction |
|---|---|---|
| Blood and lymphatic system disorders | Frequency unknown | Leucopenia |
| Immune system | Less frequent | Allergic reactions including angioedema, urticaria and anaphylaxis |
| Vascular disorders | Frequent | Hot flushes, oedema |
| | Frequency unknown | Thrombophlebitis |
| Hepato-biliary disorders | Frequent | Increased alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase |
| | Less frequent | Increased gamma-GT and bilirubin, hepatitis |
| Musculoskeletal, connective tissue and bone disorders | Less frequent | Joint pain/stiffness |
| | Frequency unknown | Myalgia, arthralgia |
| General disorders and administrative site conditions | Frequent | Asthaenia, fever, flu-like syndrome |
| Reproductive system and breast disorders | Frequent | Vaginal bleeding, vaginal dryness |
| | Frequent | Hair thinning, rash |

| | | |
|---|---|---|
| Skin and subcutaneous tissue disorders | Less frequent | Erythema multiforme, Steven-Johnson syndrome |
| Gastrointestinal disorder | Frequent | Nausea, diarrhoea, vomiting |
| Nervous system disorders | Frequent | Headache, Carpal Tunnel Syndrome, dizziness, drowsiness |
| | Less frequent | Somnolence |
| Metabolism and nutrition disorders | Less frequent | Anorexia, Hypercholesterolaemia |
| Psychiatric disorders | Frequency unknown | Depression |

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

## 4.9 Overdose

Refer to section 4.8 for symptoms of overdosage. There is no specific antidote to overdosage, and treatment must be symptomatic. 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 Stradexa is not highly protein bound. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is indicated.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

A 21.12 Hormone inhibitors

**Mechanism of action**

Anastrozole is a selective non-steroidal aromatase inhibitor.

It significantly lowers serum estradiol concentrations and has no detectable effect on formation of adrenal corticosteroids or aldosterone.

### 5.2 Pharmacokinetic properties

Anastrozole is rapidly and almost completely adsorbed from the gastro-intestinal tract following oral administration, with peak plasma concentrations occurring within about 2 hours. Food decreases the rate of absorption, though this is not considered clinically significant. It is metabolised in the liver, and excreted in urine, chiefly as metabolites. The terminal elimination half-life is about 50 hours, and steady-state concentrations are achieved after about 7 days in patients receiving once-daily doses. Anastrozole is about 40 % bound to plasma protein.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose

Magnesium stearate

Hydroxypropylmethylcellulose

Polyethylene glycol

Povidone

Sodium starch glycolate

Titanium dioxide.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store at or below 25 °C.

Do not remove from outer container until required for use.

### 6.5 Nature and contents of container

Stradexa tablets are packaged in a plain aluminium blister foil with a clear PVC film coated PVDC.

There are 3 blister strips of 10 tablets each, packed in an outer cardboard box as a pack size of 30 tablets.

### 6.6 Special precautions for disposal

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 7 HOLDER OF CERTIFICATE OF REGISTRATION

Eurolab (Pty) Ltd.

Woodmead Office Park

3 Stirrup Lane, Van Reenens Avenue

Woodmead

Gauteng

South Africa

## 8 REGISTRATION NUMBERS

A 42/21.12/0260

## 9 DATE OF FIRST AUTHORISATION

26 November 2010

## 10 DATE OF REVISION OF THE TEXT

07 May 2021