P038101

Arimidex 1 mg

anastrozole

Film-coated Tablets

Qualitative and quantitative composition
Each tablet contains 1 mg anastrozole.
For excipients see List of excipients.

Pharmaceutical Form
Film-coated tablet.
White, round, biconvex tablet with logo on one side and strength on the other.

Therapeutic Indications
Adjuvant treatment of post-menopausal women with hormone receptor positive early invasive breast cancer.

Adjuvant treatment of early breast cancer in hormone receptor positive post-menopausal women who have received 2 to 3 years of adjuvant tamoxifen.

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

Posology and method of administration

Adults including the elderly	:	One 1 mg tablet to be taken orally once a day.
Children	:	Not recommended for use in children (see Pharmacodynamic and Pharmacokinetic properties).
Renal Impairment	:	No dose change is recommended in patients with mild or moderate renal impairment.
Hepatic Impairment	:	No dose change is recommended in patients with mild hepatic disease.

For early disease, the recommended duration of treatment should be 5 years.

Contraindications
Arimidex is contraindicated in:
- pre-menopausal women
- pregnant or lactating women
- patients with severe renal impairment (creatinine clearance less than 30 ml/min)
- patients with moderate or severe hepatic disease
- patients with known hypersensitivity to anastrozole or to any of the excipients as referenced in the List of excipients.

Co-administration of tamoxifen or oestrogen-containing therapies with Arimidex should be avoided as this may diminish its pharmacological action (see Interactions with other medicinal products and other forms of interaction).

Special warnings and precautions for use
Arimidex is not recommended for use in children as safety and efficacy have not been established in this group of patients (see Pharmacodynamic and Pharmacokinetic properties).

There are no data to support the safe use of Arimidex in patients with moderate or severe hepatic impairment, or patients with severe impairment of renal function (creatinine clearance less than 30 ml/min).

Women with osteoporosis or at risk of osteoporosis should have their bone mineral density formally assessed by bone densitometry e.g. DEXA scanning at the commencement of treatment and at regular intervals thereafter. Treatment or prophylaxis for osteoporosis should be initiated as appropriate and carefully monitored.

There are no data available for the use of anastrozole with LHRH analogues. This combination should not be used outside clinical trials.

As Arimidex lowers circulating oestrogen levels it may cause a reduction in bone mineral density with a possible consequent increased risk of fracture. The use of bisphosphonates may stop further bone mineral loss caused by Arimidex in postmenopausal women and could be considered.

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interactions with other medicinal products and other forms of interaction
Antipyrine and cimetidine clinical interaction studies indicate that the co-administration of Arimidex with other drugs is unlikely to result in clinically significant drug interactions mediated by cytochrome P450.

A review of the clinical trial safety database did not reveal evidence of clinically significant interaction in patients treated with Arimidex who also received other commonly prescribed drugs. There were no clinically significant interactions with bisphosphonates (see Pharmacodynamic properties).

Co-administration of tamoxifen or oestrogen-containing therapies with Arimidex should be avoided as this may diminish its pharmacological action (see Contraindications).

Pregnancy and lactation
Arimidex is contraindicated in pregnant or lactating women.

Effects on ability to drive and use machines
Arimidex is unlikely to impair the ability of patients to drive and operate machinery. However, asthenia and somnolence have been reported with the use of Arimidex and caution should be observed when driving or operating machinery while such symptoms persist.

Undesirable effects
Unless specified, the following frequency categories were calculated from the number of adverse events reported in a large phase III study conducted in 9366 postmenopausal women with operable breast cancer treated for five years (ATAC study).

Frequency	System Organ Class	Adverse reaction
Very common (≥ 10%)	*Vascular:*	Hot flushes, mainly mild or moderate in nature.
	General:	Asthenia, mainly mild or moderate in nature.
	Musculoskeletal and connective tissue disorders:	Arthralgia/Joint stiffness Arthritis
	Nervous system:	Headache, mainly mild or moderate in nature.
	Gastrointestinal:	Nausea, mainly mild or moderate in nature.
	Skin and subcutaneous tissue:	Rash, mainly mild or moderate in nature.
Common (≥ 1% and < 10%)	*Skin and subcutaneous tissue:*	Hair thinning (Alopecia), mainly mild or moderate in nature. Allergic reactions.
	Gastrointestinal:	Diarrhoea, mainly mild or moderate in nature. Vomiting, mainly mild or moderate in nature.
	Nervous system:	Somnolence, mainly mild or moderate in nature. Carpal Tunnel Syndrome*. Sensory disturbances (including paraesthesia, taste loss and taste perversion).
	Hepatobiliary disorders:	Increases in alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase.
	Reproductive system and breast:	Vaginal dryness, mainly mild or moderate in nature. Vaginal bleeding, mainly mild or moderate in nature**.
	Metabolism and nutrition:	Anorexia, mainly mild in nature. Hypercholesterolaemia, mainly mild or moderate in nature.
	Musculoskeletal and connective tissue disorders	Bone pain, Myalgia
Uncommon (≥ 0.1% and <1%)	*Metabolism and nutrition:*	Hypercalcaemia (with or without an increase in parathyroid hormone)
	Hepatobiliary disorders:	Increases in gamma-GT and bilirubin. Hepatitis.
	Skin and subcutaneous tissue:	Urticaria.
	Musculoskeletal and connective tissue disorders:	Trigger finger.
Rare (≥ 0.01% and <0.1%)	*Skin and subcutaneous tissue:*	Erythema multiforme. Anaphylactoid reaction. Cutaneous vasculitis (including some reports of Henoch-Schönlein purpura)
Very rare (<0.01%)	*Skin and subcutaneous tissue:*	Stevens-Johnson syndrome. Angioedema.

* Events of Carpal Tunnel Syndrome have been reported in patients receiving Arimidex treatment in clinical trials in greater numbers than those receiving treatment with tamoxifen. However, the majority of these events occurred in patients with identifiable risk factors for the development of the condition.

**Vaginal bleeding has been reported commonly, mainly in patients with advanced breast cancer during the first few weeks after changing from existing hormonal therapy to treatment with Arimidex. If bleeding persists, further evaluation should be considered.

As Arimidex lowers circulating oestrogen levels, it may cause a reduction in bone mineral density placing some patients at a higher risk of fracture (see Special warnings and precautions for use).

The table below presents the frequency of pre-specified adverse events in the ATAC study, irrespective of causality, reported in patients receiving trial therapy and up to 14 days after cessation of trial therapy.

Adverse effects	Arimidex (N=3092)		Tamoxifen (N=3094)	
Hot flushes	1104	(35.7%)	1264	(40.9%)
Joint pain/stiffness	1100	(35.6%)	911	(29.4%)
Mood disturbances	597	(19.3%)	554	(17.9%)
Fatigue/asthenia	575	(18.6%)	544	(17.6%)
Nausea and vomiting	393	(12.7%)	384	(12.4%)
Fractures	315	(10.2%)	209	(6.8%)
Fractures of the spine, hip, or wrist/Colles	133	(4.3%)	91	(2.9%)
Wrist/Colles fractures	67	(2.2%)	50	(1.6%)
Spine fractures	43	(1.4%)	22	(0.7%)
Hip fractures	28	(0.9%)	26	(0.8%)
Cataracts	182	(5.9%)	213	(6.9%)
Vaginal bleeding	167	(5.4%)	317	(10.2%)
Ischaemic cardiovascular disease	127	(4.1%)	104	(3.4%)
Angina pectoris	71	(2.3%)	51	(1.6%)
Myocardial infarct	37	(1.2%)	34	(1.1%)
Coronary artery disorder	25	(0.8%)	23	(0.7%)
Myocardial ischaemia	22	(0.7%)	14	(0.5%)
Vaginal discharge	109	(3.5%)	408	(13.2%)
Any venous thromboembolic event	87	(2.8%)	140	(4.5%)
Deep venous thromboembolic events including PE	48	(1.6%)	74	(2.4%)
Ischaemic cerebrovascular events	62	(2.0%)	88	(2.8%)
Endometrial cancer	4	(0.2%)	13	(0.6%)

Fracture rates of 22 per 1000 patient-years and 15 per 1000 patient-years were observed for the Arimidex and tamoxifen groups, respectively, after a median follow-up of 68 months. The observed fracture rate for Arimidex is similar to the range reported in age-matched post-menopausal populations. It has not been determined whether the rates of fracture and osteoporosis seen in ATAC in patients on anastrozole treatment reflect a protective effect of tamoxifen, a specific effect of anastrozole, or both.

The incidence of osteoporosis was 10.5% in patients treated with Arimidex and 7.3% in patients treated with tamoxifen.

Overdose
There is limited clinical experience of accidental overdosage. In animal studies, anastrozole demonstrated low acute toxicity. Clinical trials have been conducted with various dosages of Arimidex, up to 60 mg in a single dose given to healthy male volunteers and up to 10 mg daily given to post-menopausal women with advanced breast cancer; these dosages were well tolerated. A single dose of Arimidex that results in life-threatening symptoms has not been established. There is no specific antidote to overdosage and treatment must be symptomatic.

In the management of an overdose, consideration should be given to the possibility that multiple agents may have been taken. Vomiting may be induced if the patient is alert. Dialysis may be helpful because Arimidex is not highly protein bound. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is indicated.

Pharmacodynamic properties
ATC Code: L02B G03 (Enzyme inhibitors)

Arimidex is a potent and highly selective non-steroidal aromatase inhibitor. In post-menopausal women, oestradiol is produced primarily from the conversion of androstenedione to oestrone through the aromatase enzyme complex in peripheral tissues. Oestrone is subsequently converted to oestradiol. Reducing circulating oestradiol levels has been shown to produce a beneficial effect in women with breast cancer. In post-menopausal women, Arimidex at a daily dose of 1 mg produced oestradiol suppression of greater than 80% using a highly sensitive assay.

Arimidex does not possess any progestogenic, androgenic or oestrogenic activity.

Daily doses of Arimidex up to 10 mg do not have any effect on cortisol or aldosterone secretion, measured before or after standard ACTH challenge testing. Corticoid supplements are therefore not needed.

Primary adjuvant treatment of early breast cancer
In a large phase III study conducted in 9366 post-menopausal women with operable breast cancer treated for 5 years, Arimidex was shown to be statistically superior to tamoxifen in disease-free survival. A greater magnitude of benefit was observed for disease-free survival in favour of Arimidex versus tamoxifen for the prospectively defined hormone receptor positive population. Arimidex was statistically superior to tamoxifen in time to recurrence. The difference was of even greater magnitude than in disease-free survival for both the Intention To Treat (ITT) population and hormone receptor positive population. Arimidex was statistically superior to tamoxifen in terms of time to distant recurrence. The incidence of contralateral breast cancer was statistically reduced for Arimidex compared to tamoxifen. Following 5 years of therapy, anastrozole is at least as effective as tamoxifen in terms of overall survival. However, due to low death rates, additional follow-up is required to determine more precisely the long-term survival for anastrozole relative to tamoxifen. With 68 months median follow-up, patients in the ATAC study have not been followed up for sufficient time after 5 years of treatment, to enable a comparison of long-term post treatment effects of Arimidex relative to tamoxifen.

ATAC endpoint summary: 5-year treatment completion analysis

Efficacy endpoints	Number of events (frequency)			
	Intention-to-treat population		Hormone-receptor-positive tumour status	
	Arimidex (N=3125)	Tamoxifen (N=3116)	Arimidex (N=2618)	Tamoxifen (N=2598)
Disease-free survival[a]	575 (18.4)	651 (20.9)	424 (16.2)	497 (19.1)
Hazard ratio	0.87		0.83	
2-sided 95% CI	0.78 to 0.97		0.73 to 0.94	
p-value	0.0127		0.0049	
Distant disease-free survival[b]	500 (16.0)	530 (17.0)	370 (14.1)	394 (15.2)
Hazard ratio	0.94		0.93	
2-sided 95% CI	0.83 to 1.06		0.80 to 1.07	
p-value	0.2850		0.2838	
Time to recurrence[c]	402 (12.9)	498 (16.0)	282 (10.8)	370 (14.2)
Hazard ratio	0.79		0.74	
2-sided 95% CI	0.70 to 0.90		0.64 to 0.87	
p-value	0.0005		0.0002	
Time to distant recurrence[d]	324 (10.4)	375 (12.0)	226 (8.6)	265 (10.2)
Hazard ratio	0.86		0.84	
2-sided 95% CI	0.74 to 0.99		0.70 to 1.00	
p-value	0.0427		0.0559	
Contralateral breast primary	35 (1.1)	59 (1.9)	26 (1.0)	54 (2.1)
Odds ratio	0.59		0.47	
2-sided 95% CI	0.39 to 0.89		0.30 to 0.76	
p-value	0.0131		0.0018	
Overall survival[e]	411 (13.2)	420 (13.5)	296 (11.3)	301 (11.6)
Hazard ratio	0.97		0.97	
2-sided 95% CI	0.85 to 1.12		0.83 to 1.14	
p-value	0.7142		0.7339	

a Disease-free survival includes all recurrence events and is defined as the first occurrence of loco-regional recurrence, contralateral new breast cancer, distant recurrence or death (for any reason).
b Distant disease-free survival is defined as the first occurrence of distant recurrence or death (for any reason).
c Time to recurrence is defined as the first occurrence of loco-regional recurrence, contralateral new breast cancer, distant recurrence or death due to breast cancer.
d Time to distant recurrence is defined as the first occurrence of distant recurrence or death due to breast cancer.
e Number (%) of patients who had died.

Area for text

Edge code area

Font information
Font family: **Nimbus Sans**
Body text size: **7.0 pt**

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Perigord Job No.:	227249
Market:	Standard English
Version No.:	02
Date & Time:	17 April 2014 12:35
Ops Component Code:	P038101
Drawing Ref:	630170L4
Pharma Code:	1747
Description:	Arimidex leaflet

Printable Colours: Black

Non Print: Profile, Technical Info

Perigord premedia

Drawing Ref: 630170L4
Dimensions (mm):
Length: 630.00
Width: 170.00
Version: 2 - 15.01.2014
Created by: JH
Ops site: Macclesfield

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Bar prints 100mm @ 100%

As with all treatment decisions, women with breast cancer and their physician should assess the relative benefits and risks of the treatment.

When Arimidex and tamoxifen were co-administered, the efficacy and safety were similar to tamoxifen when given alone, irrespective of hormone receptor status. The exact mechanism of this is not yet clear. It is not believed to be due to a reduction in the degree of oestradiol suppression produced by Arimidex.

Adjuvant treatment of early breast cancer for patients being treated with adjuvant tamoxifen
In a phase III trial (ABCSG 8) conducted in 2579 post-menopausal women with hormone receptor positive early breast cancer who had received surgery with or without radiotherapy and no chemotherapy, switching to Arimidex after 2 years adjuvant treatment with tamoxifen was statistically superior in disease-free survival when compared to remaining on tamoxifen, after a median follow-up of 24 months.

Time to any recurrence, time to local or distant recurrence and time to distant recurrence confirmed a statistical advantage for Arimidex, consistent with the results of disease-free survival. The incidence of contralateral breast cancer was very low in the two treatment arms with a numerical advantage for Arimidex. Overall survival was similar for the two treatment groups.

ABCSG 8 trial endpoint and results summary

Efficacy endpoints	**Number of events (frequency)**	
	Arimidex (N=1297)	**Tamoxifen (N=1282)**
Disease-free survival	65 (5.0)	93 (7.3)
Hazard ratio	0.67	
2-sided 95% CI	0.49 to 0.92	
p-value	0.014	
Time to any recurrence	36 (2.8)	66 (5.1)
Hazard ratio	0.53	
2-sided 95% CI	0.35 to 0.79	
p-value	0.002	
Time to local or distant recurrence	29 (2.2)	51 (4.0)
Hazard ratio	0.55	
2-sided 95% CI	0.35 to 0.87	
p-value	0.011	
Time to distant recurrence	22(1.7)	41(3.2)
Hazard ratio	0.52	
2-sided 95% CI	0.31 to 0.88	
p-value	0.015	
New contralateral breast cancer	7 (0.5)	15 (1.2)
Odds ratio	0.46	
2-sided 95% CI	0.19 to 1.13	
p-value	0.090	
Overall survival	43(3.3)	45 (3.5)
Hazard ratio	0.96	
2-sided 95% CI	0.63 to 1.46	
p-value	0.840	

Two further similar trials (GABG/ARNO 95 and ITA), in one of which patients had received surgery and chemotherapy, as well as a combined analysis of ABCSG 8 and GABG/ARNO 95, supported these results.

The Arimidex safety profile in these 3 studies was consistent with the known safety profile established in post-menopausal women with hormone receptor positive early breast cancer.

Study of anastrozole with the bisphosphonate risedronate (SABRE)

Bone Mineral Density (BMD)
In the phase III/IV SABRE study, 234 postmenopausal women with hormone receptor positive early breast cancer scheduled for treatment with Arimidex 1 mg/day were stratified to low, moderate and high risk groups according to their existing risk of fragility fracture. The primary efficacy parameter was the analysis of lumbar spine bone mass density using DEXA scanning. All patients received treatment with vitamin D and calcium. Patients in the low risk group received Arimidex alone (N=42), those in the moderate group were randomised to Arimidex plus risedronate 35 mg once a week (N=77) or Arimidex plus placebo (N=77) and those in the high risk group received Arimidex plus risedronate 35 mg once a week (N=38). The primary endpoint was change from baseline in lumbar spine bone mass density at 12 months.

The 12-month main analysis has shown that patients already at moderate to high risk of fragility fracture showed no decrease in their bone mass density (assessed by lumbar spine bone mineral density using DEXA scanning) when managed by using Arimidex 1 mg/day in combination with risedronate 35 mg once a week. In addition, a decrease in BMD which was not statistically significant was seen in the low risk group treated with Arimidex 1 mg/day alone. These findings were mirrored in the secondary efficacy variable of change from baseline in total hip BMD at 12 months.

This study provides evidence that the use of bisphosphonates should be considered in the management of possible bone mineral loss in postmenopausal women with early breast cancer scheduled to be treated with Arimidex.

Lipids
In the SABRE study there was a neutral effect on plasma lipids in those patients treated with Arimidex plus risedronate.

Paediatrics
Three clinical trials were conducted in paediatric patients (2 in pubertal boys with gynaecomastia and 1 in girls with McCune-Albright Syndrome).

Gynaecomastia studies
Trial 0006 was a randomised, double-blind, multi-centre study of 82 pubertal boys (aged 11-18 years inclusive) with gynaecomastia of greater than 12 months duration treated with Arimidex 1 mg/day or placebo daily for up to 6 months. No significant difference in the number of patients who had a 50% or greater reduction in total breast volume after 6 months of treatment was observed between the Arimidex 1 mg treated group and the placebo group.

Trial 0001 was an open-label, multiple-dose pharmacokinetic study of Arimidex 1 mg/day in 36 pubertal boys with gynaecomastia of less than 12 months duration. The secondary objectives were to evaluate the proportion of patients with reductions from baseline in the calculated volume of gynaecomastia of both breasts combined of at least 50% between day 1 and after 6 months of study treatment, and patient tolerability and safety.
A pharmacodynamic subpopulation of 25 boys was selected in this study to explore the potential benefits of anastrozole. It was noted a decrease in total breast volume of 50% or greater at 6 months was seen in 55.6% (as measured by ultrasound) and 77.8% (as measured by caliper) of the boys (observational data only, no statistical analysis conducted on these results).

McCune-Albright Syndrome study
Trial 0046 was an international, multi-centre, open-label exploratory trial of Arimidex in 28 girls (aged 2 to ≤10 years) with McCune-Albright Syndrome (MAS). The primary objective was to evaluate the safety and efficacy of Arimidex 1 mg/day in patients with MAS. The efficacy of study treatment was based on the proportion of patients fulfilling defined criteria relating to vaginal bleeding, bone age, and growth velocity.

No statistically significant change in the frequency of vaginal bleeding days on treatment was observed. There were no clinically significant changes in Tanner staging, mean ovarian volume or mean uterine volume. No statistically significant change in the rate of increase in bone age on treatment compared to the rate during baseline was observed. Growth rate (in cm/year) was significantly reduced ($p<0.05$) from pre-treatment through month 0 to month 12, and from pre-treatment to the second 6 months (month 7 to month 12). Of the patients with baseline vaginal bleeding, 28% experienced a ≥50% reduction in the frequency of bleeding days on treatment; 40% experienced a cessation over a 6-month period, and 12% experienced a cessation over a 12-month period.

The overall assessment of the adverse events in children less than 18 years of age raised no safety or tolerability concerns.

Pharmacokinetic properties
Absorption of anastrozole is rapid and maximum plasma concentrations typically occur within two hours of dosing (under fasted conditions). Anastrozole is eliminated slowly with a plasma elimination half-life of 40 to 50 hours. Food slightly decreases the rate but not the extent of absorption. The small change in the rate of absorption is not expected to result in a clinically significant effect on steady-state plasma concentrations during once daily dosing of Arimidex tablets. Approximately 90 to 95% of plasma anastrozole steady-state concentrations are attained after 7 daily doses. There is no evidence of time or dose-dependency of anastrozole pharmacokinetic parameters.

Anastrozole pharmacokinetics are independent of age in post-menopausal women.

Anastrozole is only 40% bound to plasma proteins.

In boys with pubertal gynaecomastia, anastrozole was rapidly absorbed, was widely distributed, and was eliminated slowly with a half-life of approximately 2 days. Clearance of anastrozole was lower in girls than in boys and exposure higher. Anastrozole in girls was widely distributed and slowly eliminated, with an estimated half-life of approximately 0.8 days.

Anastrozole is extensively metabolised by post-menopausal women with less than 10% of the dose excreted in the urine unchanged within 72 hours of dosing. Metabolism of anastrozole occurs by N-dealkylation, hydroxylation and glucuronidation. The metabolites are excreted primarily via the urine. Triazole, the major metabolite in plasma, does not inhibit aromatase.

The apparent oral clearance of anastrozole in volunteers with stable hepatic cirrhosis or renal impairment was in the range observed in healthy volunteers.

Preclinical safety data relevant to the prescriber

Acute toxicity
In acute toxicity studies in rodents the median lethal dose of anastrozole was greater than 100 mg/kg/day by the oral route and greater than 50 mg/kg/day by the intraperitoneal route. In an oral acute toxicity study in the dog the median lethal dose was greater than 45 mg/kg/day.

Chronic toxicity
Multiple dose toxicity studies utilised rats and dogs. No no-effect levels were established for anastrozole in the toxicity studies, but those effects that were observed at the low doses (1 mg/kg/day) and mid doses (dog 3 mg/kg/day; rat 5 mg/kg/day) were related to either the pharmacological or enzyme-inducing properties of anastrozole and were unaccompanied by significant toxic or degenerative changes.

Mutagenicity
Genetic toxicology studies with anastrozole show that it is not a mutagen or a clastogen.

Reproductive toxicology
Oral administration of anastrozole to female rats produced a high incidence of infertility at 1 mg/kg/day and increased pre-implantation loss at 0.02 mg/kg/day. These effects occurred at clinically relevant doses. An effect in man cannot be excluded. These effects were related to the pharmacology of the compound and were completely reversed after a 5-week compound withdrawal period.

Oral administration of anastrozole to pregnant rats and rabbits caused no teratogenic effects at doses up to 1.0 and 0.2 mg/kg/day respectively. Those effects that were seen (placental enlargement in rats and pregnancy failure in rabbits) were related to the pharmacology of the compound.

The survival of litters born to rats given anastrozole at 0.02 mg/kg/day and above (from day 17 of pregnancy to day 22 post-partum) was compromised. These effects were related to the pharmacological effects of the compound on parturition. There were no adverse effects on behaviour or reproductive performance of the first generation offspring attributable to maternal treatment with anastrozole.

Carcinogenicity
A two year rat oncogenicity study resulted in an increase in incidence of hepatic neoplasms and uterine stromal polyps in females and thyroid adenomas in males at the high dose (25 mg/kg/day) only. These changes occurred at a dose which represents 100-fold greater exposure than occurs at human therapeutic doses, and are considered not to be clinically relevant to the treatment of patients with anastrozole.

A two year mouse oncogenicity study resulted in the induction of benign ovarian tumours and a disturbance in the incidence of lymphoreticular neoplasms (fewer histiocytic sarcomas in females and more deaths as a result of lymphomas). These changes are considered to be mouse-specific effects of aromatase inhibition and not clinically relevant to the treatment of patients with anastrozole.

List of excipients
Lactose Monohydrate
Povidone
Sodium Starch Glycolate
Magnesium Stearate
Hypromellose
Macrogol 300
Titanium Dioxide

Incompatibilities
Not applicable.

Shelf-life
Please refer to expiry date on the blister strip or outer carton.

Special precautions for storage
Do not store above 30°C.

Pack size
Please refer to the outer carton for pack size.

Instructions for use and handling
No special requirements.

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Manufactured by AstraZeneca Pharmaceuticals LP, Newark, Delaware 19702, USA for AstraZeneca UK Limited, Macclesfield, Cheshire, United Kingdom.

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