FASLODEX®
fulvestrant

Choose Faslodex Earlier*†

*1 vs 2 prior endocrine therapies

†In postmenopausal women with hormone-receptor positive, locally advanced or metastatic breast cancer who have progressive disease following prior tamoxifen therapy[1]

PI

1. Faslodex Approved Product Information. Date of first inclusion in the ARTG: 6 March 2006. Date of most recent amendment: 29 March 2016.

PI

FASLODEX 500 mg

LEGEND

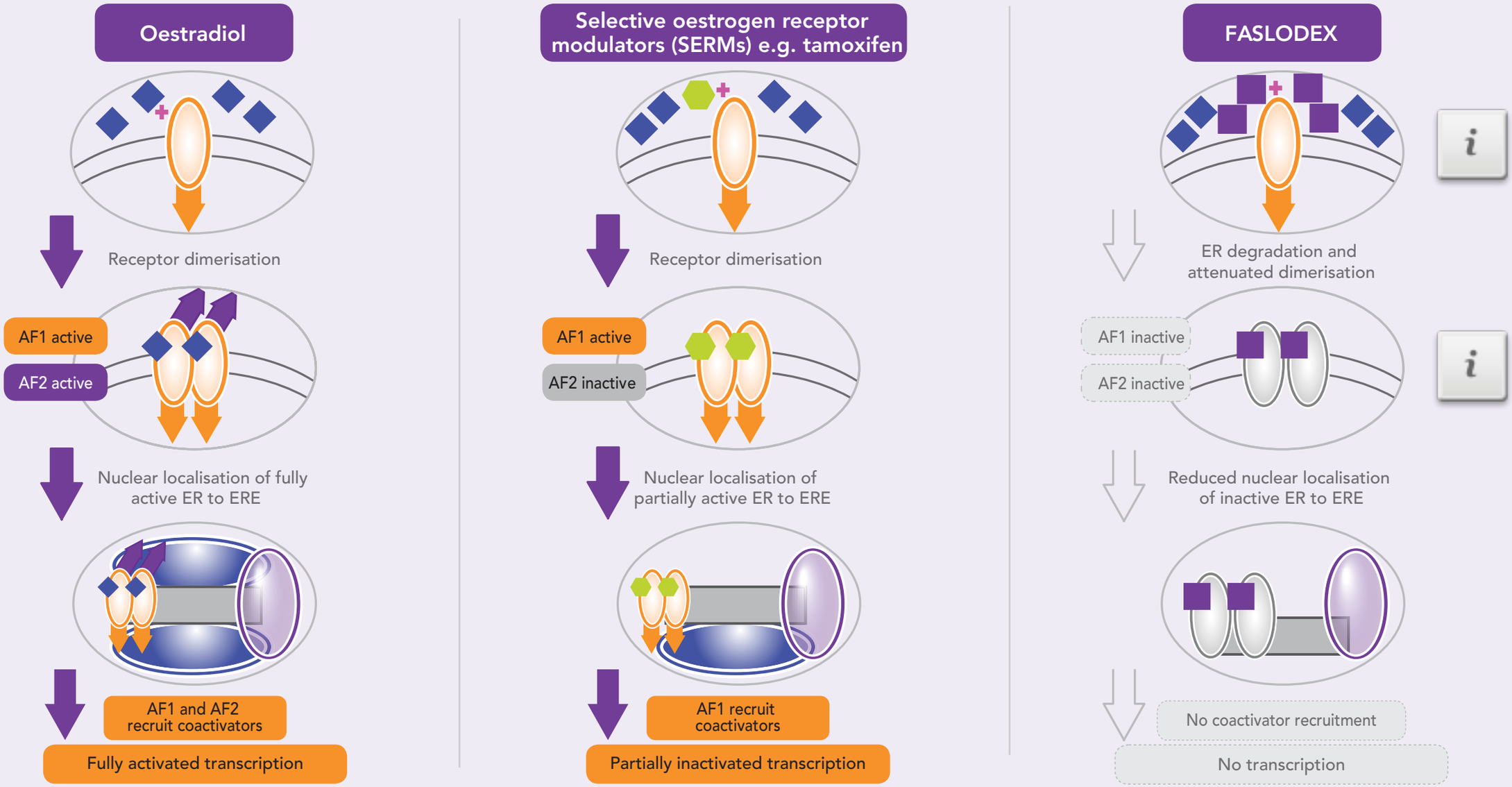
VIEW VIDEO

FASLODEX® fulvestrant

Faslodex 500 mg for postmenopausal women with ER+ locally advanced or metastatic breast cancer with disease progression following prior tamoxifen therapy[1]

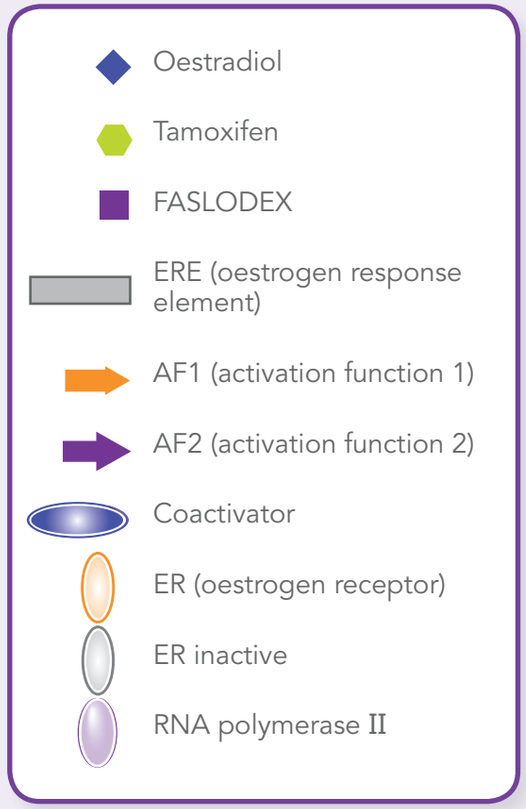
MECHANISM OF ACTION

FASLODEX is an ER antagonist with NO known agonist activity[2]



Adapted from Dowsett *et al*, 2005[4]

PI

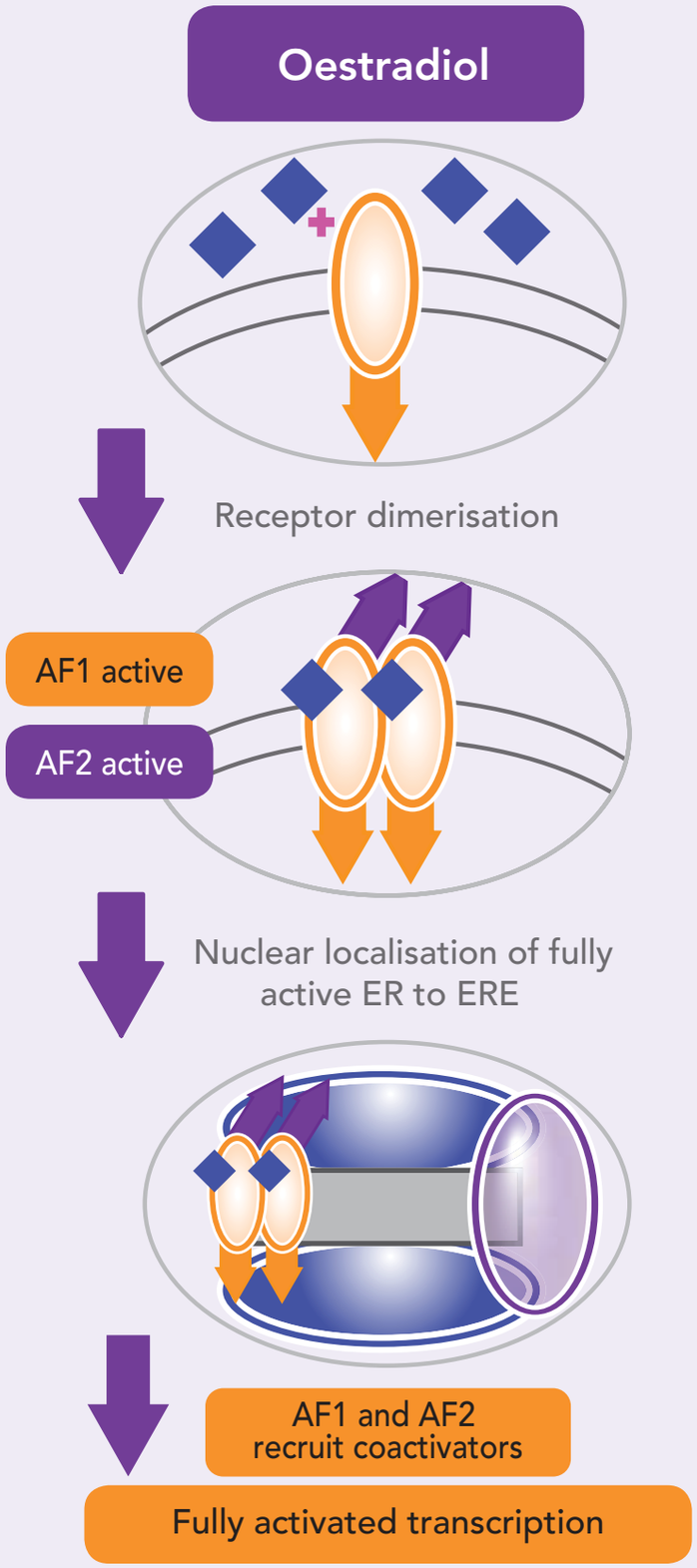


1. Faslodex Approved Product Information. Date of first inclusion in the ARTG: 6 March 2006. Date of most recent amendment: 29 March 2016.
2. Howell A. *Int J Gynecol Cancer* 2006; 16 Suppl 2: 521–3.
3. Wakeling AE. *Endocr Relat Cancer* 2000; 7(1): 17–28.
4. Dowsett M *et al. Breast Cancer Res Treat* 2005; 93 Suppl 1: S11–8.
5. Parker MG. *Breast Cancer Res Treat* 1993; 26(2): 131–7.
6. Carlson RW. *Clin Breast Cancer* 2005; 6 Suppl 1: S5–8.

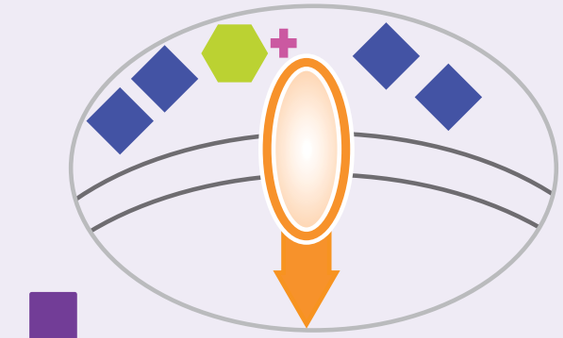
Binds competitively at the ER, creating a conformational change[2-5]

Blocks the binding of oestradiol to the ER in a dose-dependent manner[2,6]

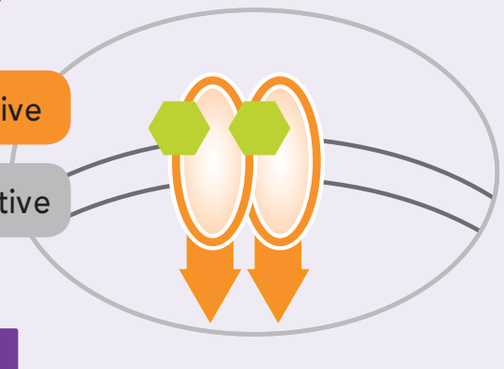
Accelerates degradation of the ER in a dose-dependent manner and inhibits both dimerisation and nuclear translocation[2,3,6]


Oestradiol
Receptor dimerisation
AF1 active
AF2 active
Nuclear localisation of fully active ER to ERE
AF1 and AF2 recruit coactivators
Fully activated transcription

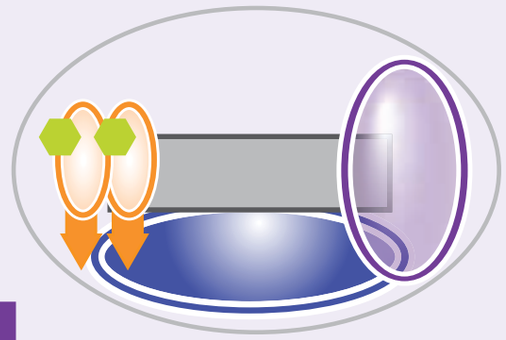
Selective oestrogen receptor modulators (SERMs) e.g. tamoxifen



Receptor dimerisation

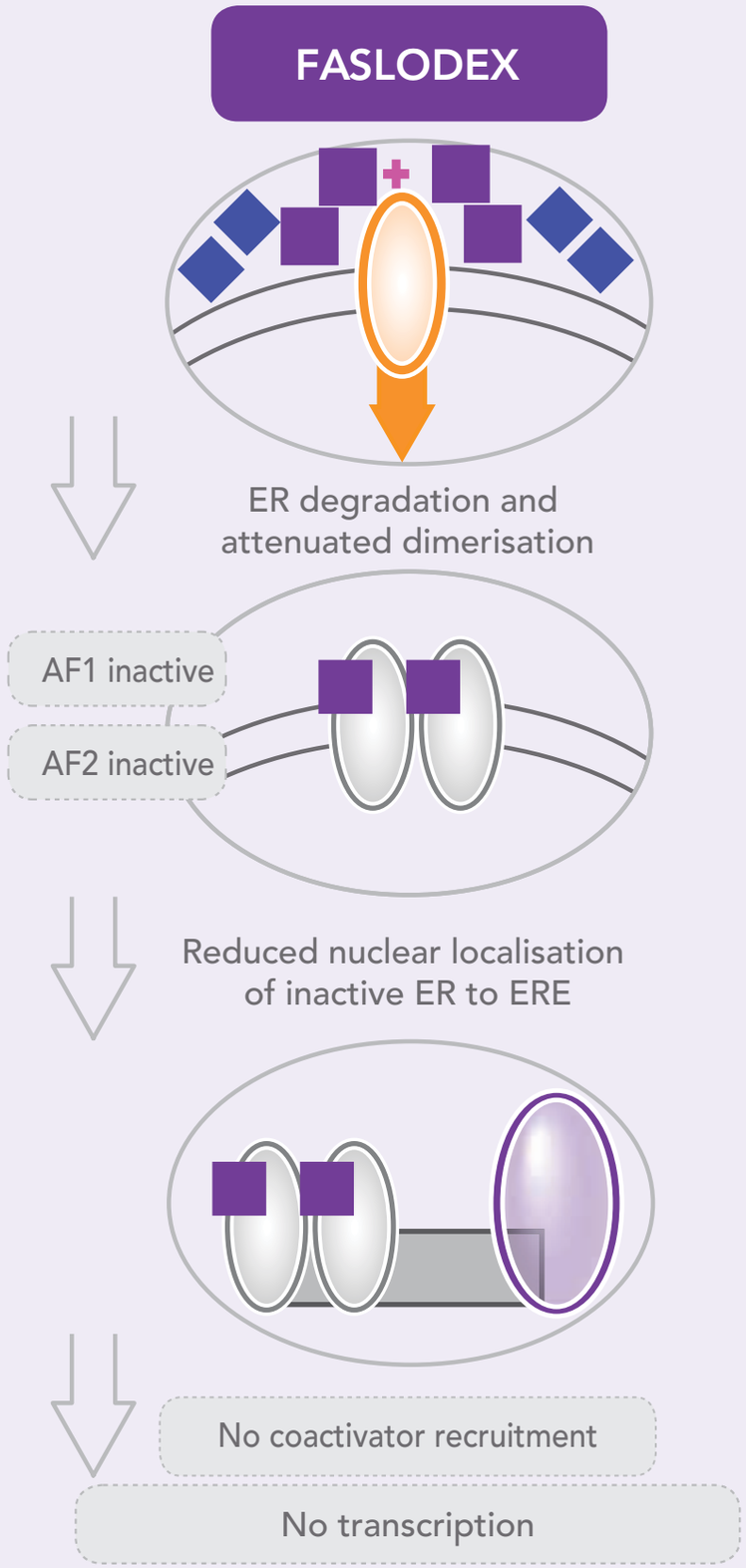


Nuclear localisation of partially active ER to ERE



AF1 recruit coactivators

Partially inactivated transcription

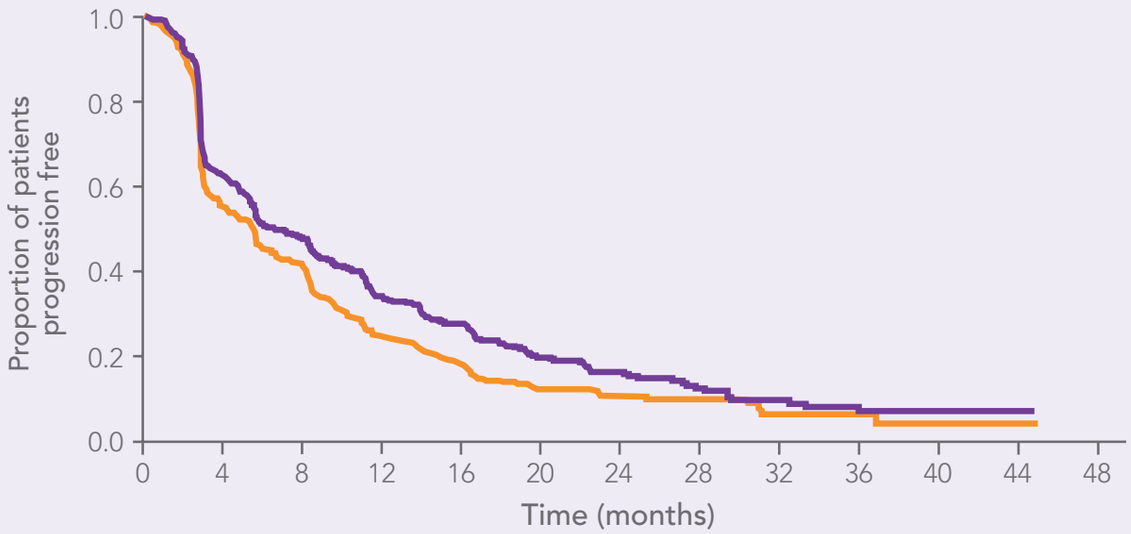

FASLODEX
ER degradation and
attenuated dimerisation
AF1 inactive
AF2 inactive
Reduced nuclear localisation
of inactive ER to ERE
No coactivator recruitment
No transcription

FASLODEX® fulvestrant

PROLONGED PROGRESSION-FREE SURVIVAL (PFS) WITH FASLODEX 500mg IN CONFIRM[1*]

- Median PFS: 6.5 months compared to 5.5 months with FASLODEX 250 mg[1]
- 20% reduction in risk of progression compared to FASLODEX 250 mg[1]

*HR=0.80; 95% CI 0.68-0.94; p=0.006 compared with FASLODEX 250 mg[1]



No. of patients at risk

FASLODEX 500 mg	362	216	163	113	90	54	37	19	12	7	3	2	0
FASLODEX 250 mg	374	199	144	85	60	35	25	12	4	3	1	1	0

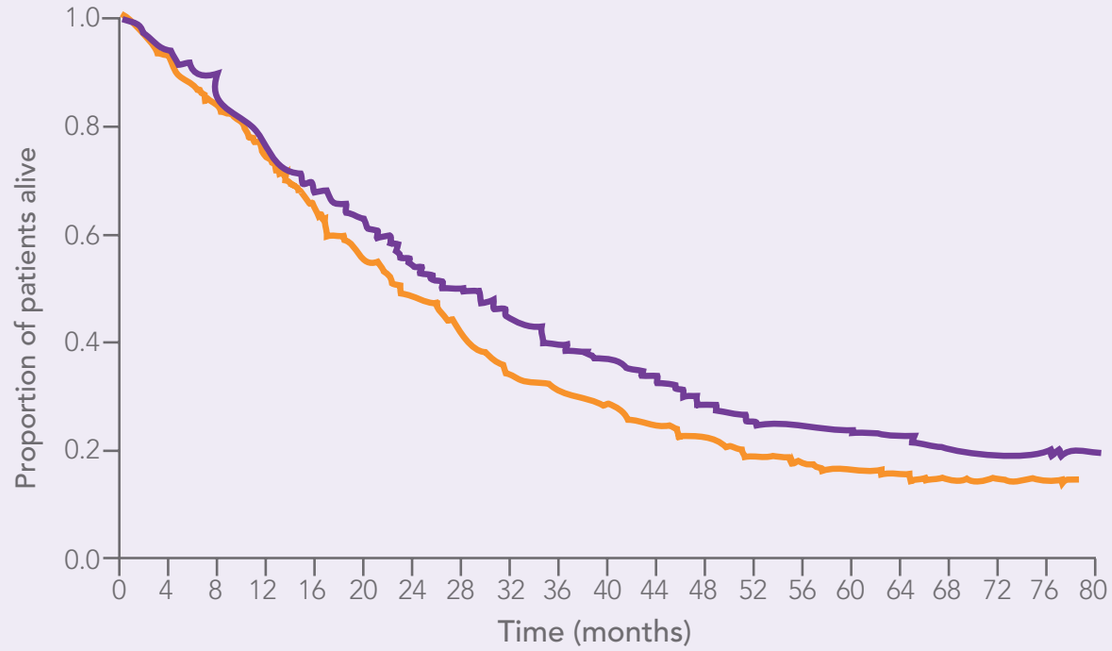
Adapted from Di Leo A *et al*, 2010.[1]

FASLODEX 500 mg FASLODEX 250 mg

CONFIRM FINAL OVERALL SURVIVAL DATA AT 75% MATURITY[2,3]

- FASLODEX 500 mg was associated with a 4.1-month increase in median OS and a 19% reduction in risk of death compared with FASLODEX 250 mg*
- Median OS was 26.4 months with FASLODEX 500 mg compared to 22.3 months with FASLODEX 250 mg[3]*

*HR=0.81; 95% CI 0.69-0.96; p=0.02 (nominal p-value as no adjustment was made for multiplicity) compared with FASLODEX 250 mg[3]



No. of patients at risk

FASLODEX 500 mg	362	333	288	254	227	202	178	163	141	123	114	98	81	64	47	30	26	15	8	1	0
FASLODEX 250 mg	374	338	299	261	223	191	164	137	112	96	87	74	64	48	37	22	14	8	3	2	0

Adapted from Di Leo A *et al*, 2014.[3]

1. Di Leo A *et al*. *J Clin Oncol* 2010; 28(30): 4594–600.
2. Faslodex Approved Product Information. Date of first inclusion in the ARTG: 6 March 2006. Date of most recent amendment: 29 March 2016.
3. Di Leo A *et al*. *J Natl Cancer Inst* 2014; 106(1):djt337. Epub 2013 Dec 7.

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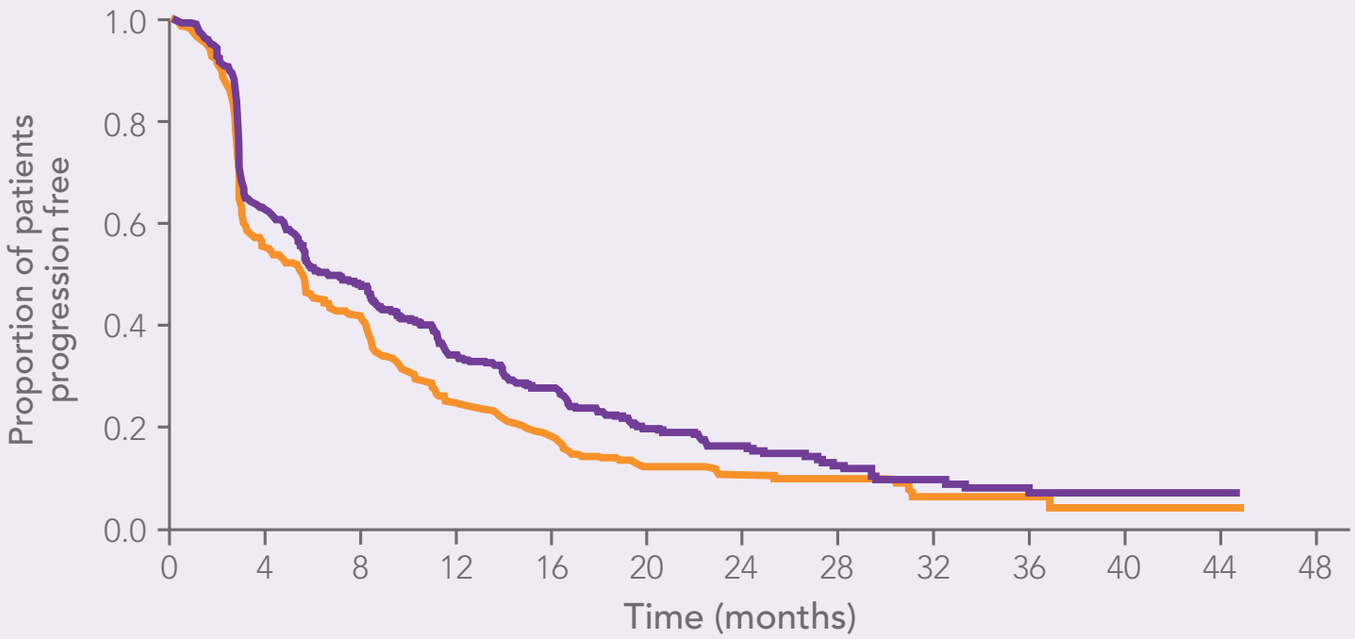

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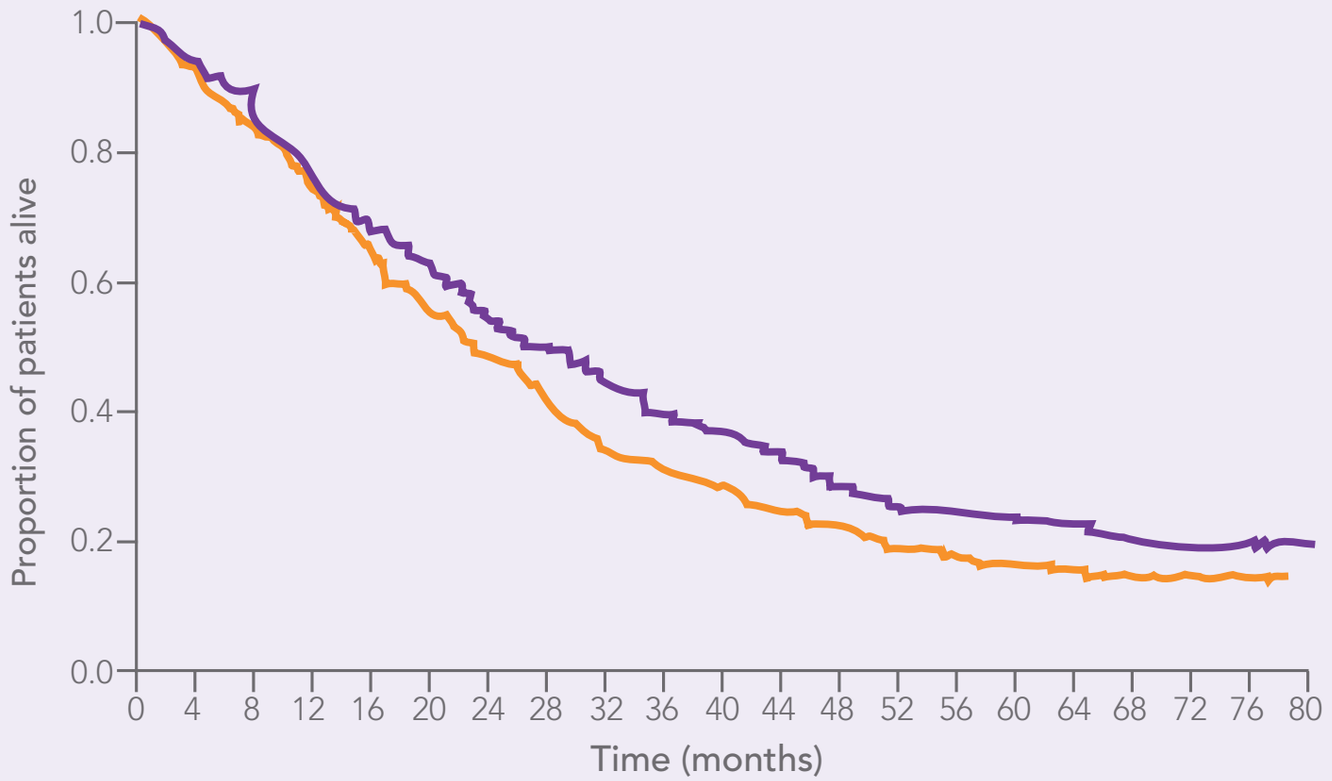

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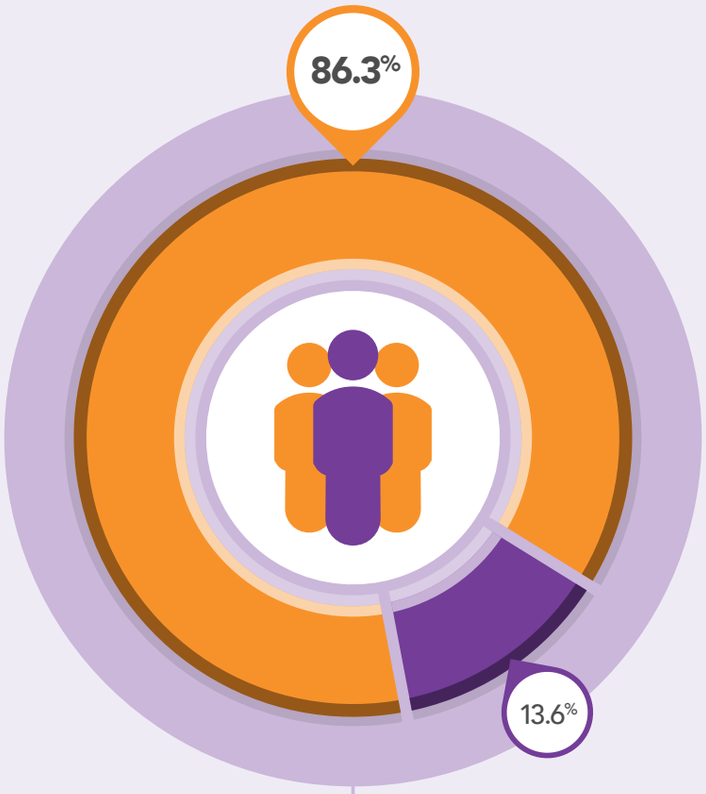
Adapted from Di Leo A *et al*, 2014.[3]

FASLODEX 500 mg FASLODEX 250 mg

PI

86% OF PATIENTS HAD ONLY 1 PRIOR ENDOCRINE THERAPY

At baseline in CONFIRM[1*†]



86.3% – 1 prior endocrine therapy[†]

VS

13.6% – 2 prior endocrine therapies[†]

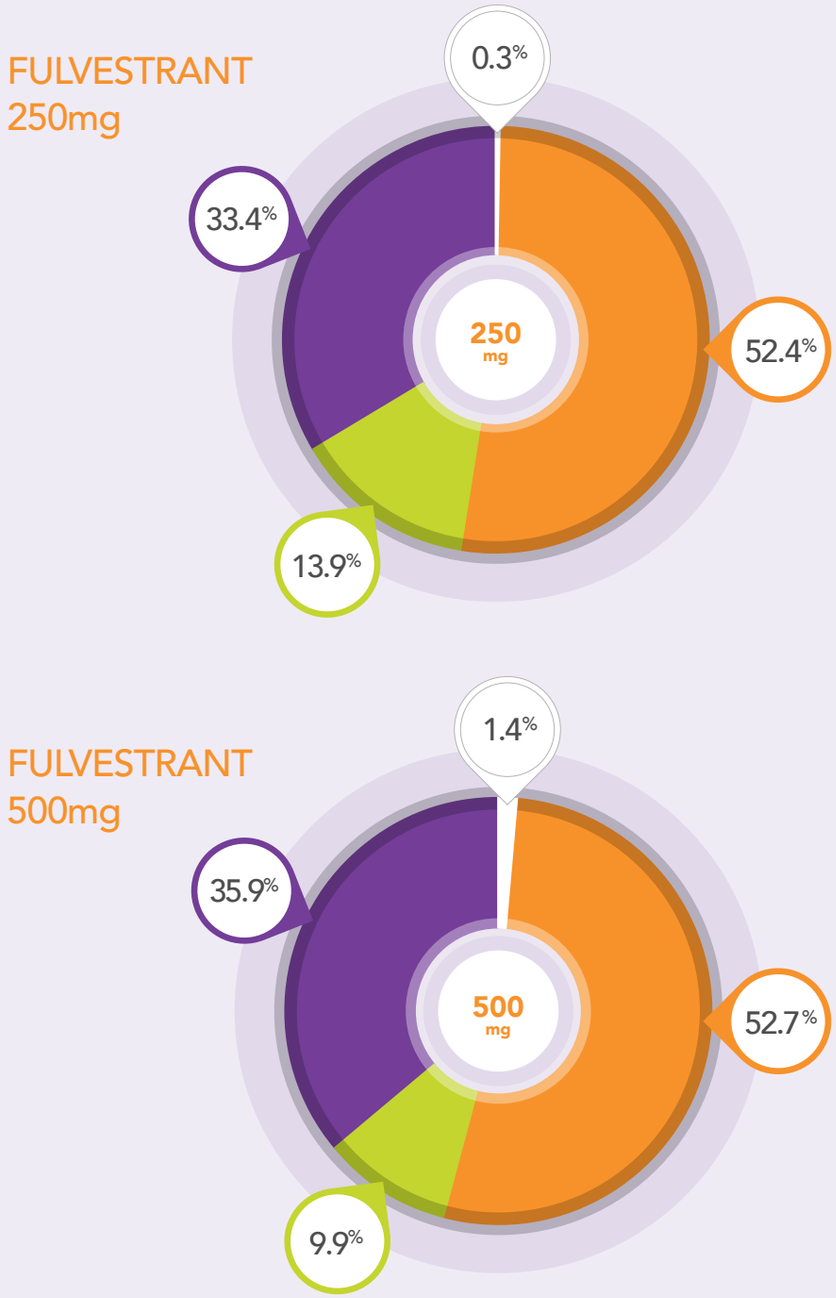
*The CONFIRM (COmparisoN of Faslodex In Recurrent or Metastatic Breast Cancer) trial was a randomised, double-blind, controlled phase III study of 736 postmenopausal women with advanced ER-positive breast cancer who had disease recurrence on or after adjuvant endocrine therapy or progression following endocrine therapy for advanced disease[2]

[†]1 patient received 0 prior endocrine therapy and was ruled ineligible for the study[2]

1. AstraZeneca Date on file
2. Di Leo A *et al*. *J Clin Oncol* 2010; 28(30): 4594–600.

PI

CONFIRM: PATIENT HISTORY AT RANDOMISATION



- **>50% had a recurrence** during or ≤12 months after completing adjuvant hormonal therapy[1†]
- **>1 in 3 had progressed** on their first-line endocrine treatment for *de novo* advanced disease[1†]

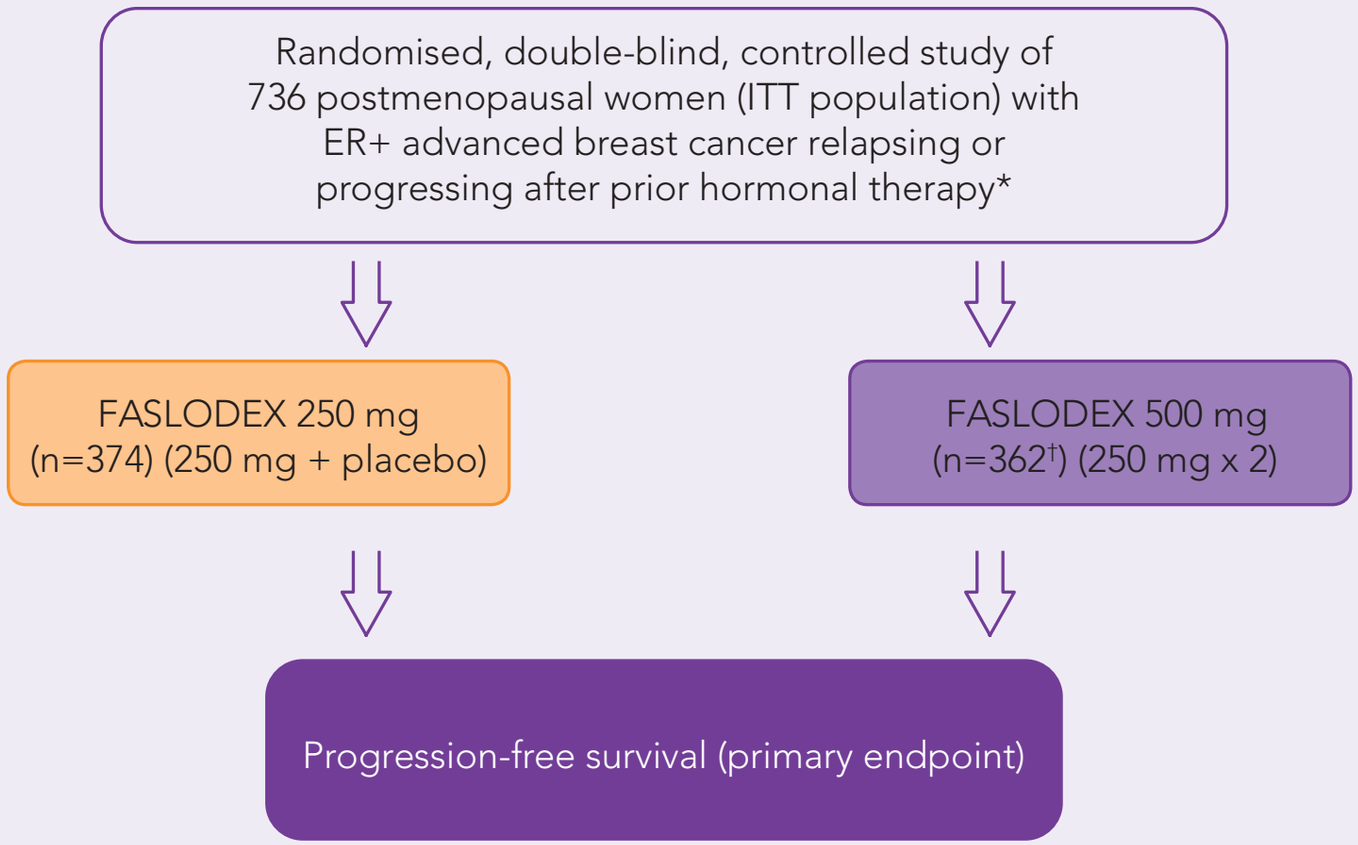
†Randomised patients from both treatment groups

- Recurrence during or ≤12 months after completing adjuvant hormonal therapy
- Recurrence >12 months after completing adjuvant hormonal therapy and after progression on 1st line endocrine therapy for advanced disease
- Progressed on 1st line endocrine treatment for *de novo* advanced disease
- Other

Adapted from Di Leo A *et al*, 2010.[1]

1. Di Leo A *et al*. *J Clin Oncol* 2010; 28(30): 4594–600.

COMPARISON OF FASLODEX IN RECURRENT OR METASTATIC BREAST CANCER (CONFIRM)[1]



Planned number of injections per month was same in both groups:[1]

- 500 mg arm: 2 x 250 mg on days 0, 14, 28, and every 28 (±3) days thereafter
- 250 mg arm: 1 x 250 mg plus 1 X placebo, same as above, except day 14 (2 placebo injections only)

*FASLODEX is indicated for postmenopausal women with ER+ locally advanced or metastatic breast cancer with disease progression following prior tamoxifen therapy[2]

†1 patient was excluded from the safety analysis for not receiving any randomised treatment

PI

1. Di Leo A *et al*. *J Clin Oncol* 2010; 28(30): 4594–600.
2. Faslodex Approved Product Information. Date of first inclusion in the ARTG: 6 March 2006. Date of most recent amendment: 29 March 2016.

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SUMMARY OF ADVERSE DRUG REACTIONS (ADR) SEEN IN CLINICAL TRIALS FOR FASLODEX 500 MG[1]

FASLODEX® fulvestrant

FREQUENCY DESCRIPTOR	SYSTEM ORDER CLASS	ADR
Very common (≥10%)	General disorders and administration site conditions Hepatobiliary disorders Gastrointestinal disorders	Injection site reactions, asthenia Elevated liver enzymes (ALT, AST, ALP)[a] Nausea
Common (≥1 – <10%)	Vascular disorders Nervous system disorders Hepatobiliary disorders Gastrointestinal disorders Metabolism and nutrition disorders Skin and subcutaneous tissue disorders Infections and infestations Immune system disorders	Hot flushes Headache Elevated bilirubin[a] Vomiting, diarrhoea Anorexia Rash Urinary tract infections Hypersensitivity reactions
Uncommon (≥0.1% and <1%)	Hepatobiliary disorders Blood and lymphatic system	Hepatic failure[b], hepatitis, elevated gamma-GT Reduced platelet count

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a. Based on any CTC grade change from baseline.

b. The event was not observed in major clinical studies (CONFIRM, FINDER1, FINDER2, NEWEST). The frequency has been calculated using the upper limit of the 95% confidence interval for the point estimate. This is calculated as 3/560 (where 560 is the number of patients in the major clinical studies), which equates to a frequency category of 'uncommon'

FASLODEX PATIENT ACCESS PROGRAMME

FASLODEX® fulvestrant

Enrol online at **www.astrazenacaoncology.com.au**

INITIAL THERAPY (First month)	SUBSEQUENT THERAPY (2nd, 3rd & 4th month)	ONGOING THERAPY (5th month onwards)
Starting dose and loading dose funded by AstraZeneca	Next 3 doses funded by patient	Further ongoing doses funded by AstraZeneca

FASLODEX DOSING

ELIGIBILITY

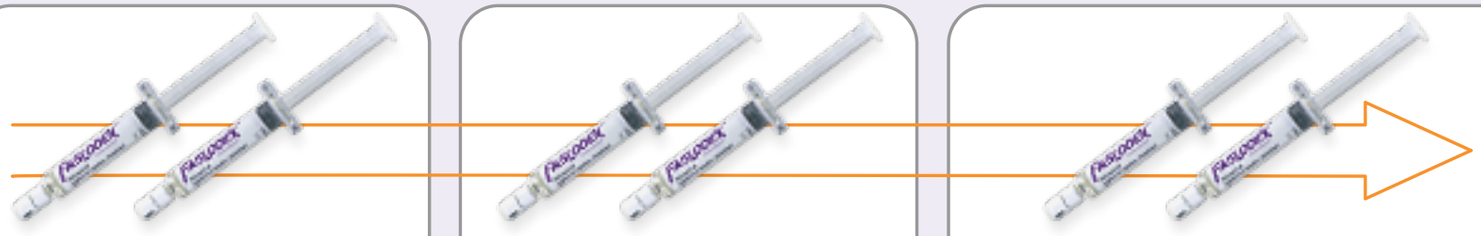
HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

PI

FASLODEX 500 mg DOSING[1]

First month (Starting doses) | **Following months**



Day 1
500 mg

Day 15 (loading dose)
500 mg

Monthly
500 mg

- To be administered intramuscularly - one injection in each buttock[1]
- The injection should be administered slowly (1-2 minutes per injection)[1]

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

1. Faslodex Approved Product Information. Date of first inclusion in the ARTG: 6 March 2006. Date of most recent amendment: 29 March 2016.

PI

WHAT ARE THE ELIGIBILITY CRITERIA FOR THE PROGRAMME?

Under this programme, AstraZeneca will supply a proportion of the patient's FASLODEX treatment free of charge for patients who:

- are using FASLODEX as per the approved indication for use in Australia: *the treatment of postmenopausal women with hormone receptor positive, locally advanced or metastatic breast cancer who have progressive disease following prior tamoxifen therapy*[1]

- are deemed appropriate to start treatment with FASLODEX 500 mg (for NEW patients)

- are deemed by their doctor to be demonstrating an ongoing clinical benefit from FASLODEX 500 mg (for patients being MAINTAINED on therapy).

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

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HOW DOES THE FASLODEX PATIENT ACCESS PROGRAMME WORK?

Step-By-Step Guide for Physicians

1. **Enrolling an eligible patient for initial treatment**

2. **Subsequent treatment – For patients demonstrating ongoing clinical benefit after their first month of treatment.**

3. **Maintenance treatment – For patients continuing to gain clinical benefit after their 4th month of treatment.**

On a monthly basis, continue to complete and return the Patient Continuation Form as described above, until the patient no longer requires FASLODEX.

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

HOW DOES THE FASLODEX PATIENT ACCESS PROGRAMME WORK?

Step-By-Step Guide for Physicians

1. Enrolling an eligible patient for initial treatment

Advise the patient of the programme and explain that the *first month is free.* They will be required to pay for 3 months of therapy (month 2, 3 and 4) if they continue on FASLODEX, being eligible for free stock again following the 4th completed month of therapy.

- To enrol a patient, complete the *Patient Registration Form* and sign, date, and *fax or email to Symbion on 1300 016 995 or symbion.map@symbion.com.au.* The *Patient Registration Form* acts as an order form for the patient's first delivery of FASLODEX so it's important that all details are accurate and that all required fields are completed. (Note that a physical address must be provided for delivery, PO boxes are not suitable).
- You can also complete patient registration online at *www.astrazenecaoncology.com.au*
  - *Write a prescription for FASLODEX* for the patient to take to the nominated pharmacy for collection of their initial month's supply of FASLODEX.
- Provide patient with the *Patient Guide* containing an overview of the programme and information on FASLODEX.
- Review patient *at least 5 days* before next injection to determine whether continuation of FASLODEX required.

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

HOW DOES THE FASLODEX PATIENT ACCESS PROGRAMME WORK?

Step-By-Step Guide for Physicians

1. Enrolling an eligible patient for initial treatment

2. Subsequent treatment – For patients demonstrating ongoing clinical benefit after their first month of treatment.

- Prescribe FASLODEX as a private prescription and advise the patient they will be required to pay for the next 3 months of therapy and to *present their prescription at their pharmacy for processing.*

3. Maintenance treatment – For patients continuing to gain clinical benefit after their 4th month of treatment.

On a monthly basis continue to complete and return the Patient Continuation Form as described above, until the patient no longer requires FASLODEX.

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

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2. **Subsequent treatment – For patients demonstrating ongoing clinical benefit after their first month of treatment.**

3. **Maintenance treatment – For patients continuing to gain clinical benefit after their 4th month of treatment.**

   Patients enrolled in the programme who have completed their fourth month of therapy and continue to gain a positive clinical benefit are eligible for continued supply of FASLODEX free of charge.

   - It is recommended that the patient is assessed to determine whether continuation of FASLODEX is required.
   - Complete the *Patient Continuation Form and fax or email to Symbion on 1300 016 995 or symbion.map@symbion.com.au.*
   - Allow 5 working days for delivery of FASLODEX.

On a monthly basis continue to complete and return the Patient Continuation Form as described above, until the patient no longer requires FASLODEX.

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

FREQUENTLY ASKED QUESTIONS

1. How long will AstraZeneca continue to fund FASLODEX under this programme?

2. How will patients receive their initial supply of stock under the programme?

3. How are orders made for additional FASLODEX stock?

4. Will AstraZeneca collect any data on patients enrolled in this programme?

5. Will health funds subsidise the cost borne by the patient for FASLODEX treatment?

6. Who do I contact if I have specific questions regarding FASLODEX or the FASLODEX Patient Access Programme?

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

PI

FREQUENTLY ASKED QUESTIONS

1. How long will AstraZeneca continue to fund FASLODEX under this programme?

The Programme is open for new enrolments until 31st December, 2016. For all patients who have entered the programme, AstraZeneca will continue to provide FASLODEX free of charge for the proportion of treatment specified until such time as:

- the doctor deems that the patient is no longer gaining any clinical benefit from treatment; or
- until FASLODEX becomes available on the PBS.

2. How will patients receive their initial supply of stock under the programme?

3. How are orders made for additional FASLODEX stock?

4. Will AstraZeneca collect any data on patients enrolled in this programme?

5. Will health funds subsidise the cost borne by the patient for FASLODEX treatment?

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

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1. **How long will AstraZeneca continue to fund FASLODEX under this programme?**

2. **How will patients receive their initial supply of stock under the programme?**

   - *Following receipt of the Patient Registration Form, Symbion will process the order.*
   - *The Patient Registration Form will secure the initial 2 doses of FASLODEX (ie: starting dose and additional loading dose required when FASLODEX is initiated)*
   - Symbion will arrange couriered delivery of FASLODEX to the pharmacy nominated on the Patient Registration Form.
   - The nominated pharmacy will store FASLODEX (refrigerated between 2 – 8°C) until patient presents for collection.
   - Please allow 5 working days for delivery of FASLODEX to the specified pharmacist. FASLODEX will not be delivered on Fridays or on a day before a public holiday to ensure the cold chain storage requirements are enforced.
   - Please contact AstraZeneca Medical Information on 1800 805 342 or via email at medinfo.australia@astrazeneca.com for any further enquiries.

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

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2. How will patients receive their initial supply of stock under the programme?

3. How are orders made for additional FASLODEX stock?

   After a patient has been registered for the programme and received four months of therapy (first month funded by AstraZeneca and subsequent months funded by the patient via private prescription) additional stock can be ordered for the patient on a monthly basis using the *Patient Continuation Form or online at www.astrazenecaoncology.com.au.*

   Following receipt of the Patient Continuation Form, Symbion will process these orders and arrange delivery of stock in the same process outlined for initial orders above.

4. Will AstraZeneca collect any data on patients enrolled in this programme?

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

FREQUENTLY ASKED QUESTIONS

3. How are orders made for additional FASLODEX stock?

4. Will AstraZeneca collect any data on patients enrolled in this programme?

AstraZeneca will only collect de-identified data for the purpose of administering the programme. *The Registration Form acts as an order form for the patient's first delivery of FASLODEX. All fields in the form must be completed to enable registration and processing of the first order of FASLODEX. Please note that the form requires a physical address be provided for the nominated pharmacy (not a PO box) to enable delivery of stock.*

5. Will health funds subsidise the cost borne by the patient for FASLODEX treatment?

6. Who do I contact if I have specific questions regarding FASLODEX or the FASLODEX Patient Access Programme?

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

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5. Will health funds subsidise the cost borne by the patient for FASLODEX treatment?

Private health funds differ in terms of policies for reimbursement of costs associated with cancer treatments and this may depend on whether the patient is receiving treatment at home or whilst in hospital. AstraZeneca advises patients to contact their policy provider and seek clarification on entitlement to claim for costs associated with this treatment.

6. Who do I contact if I have specific questions regarding FASLODEX or the FASLODEX Patient Access Programme?

ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS

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ELIGIBILITY

HOW DOES THE PROGRAMME WORK?

FREQUENTLY ASKED QUESTIONS