

Drug Facts: NOLVADEX (tamoxifen)

What is this drug for?	Reduce the chance of getting breast cancer
Who might consider taking it?	Women at high risk of getting breast cancer (1.7% or higher risk over 5 years). You can calculate your breast cancer risk at http://bcra.nci.nih.gov/btc .
Who should <u>not</u> take it?	Women who are pregnant or breastfeeding
Recommended testing	Have a yearly checkup that includes a gynecological examination and blood tests
Other things to consider doing	No other medicines are approved to reduce breast cancer risk for women who have not had breast cancer

NOLVADEX STUDY FINDINGS TABLE

13,000 women at high risk of getting breast cancer were given NOLVADEX or a sugar pill for 6 years. Here's what happened:

What difference did NOLVADEX make?	Women given a sugar pill	Women given NOLVADEX (20 mg a day)
Did NOLVADEX help?		
Fewer women got invasive breast cancer (1.1% fewer)	2.4% 24 in 1000	1.3% 13 in 1000
No difference in dying from breast cancer	About 0.07% in both groups 0.7 in 1000	
Did NOLVADEX have side effects?		
<i>Life threatening side effects</i>		
More women had a blood clot in their leg or lungs (0.3% more)	0.4% 4 in 1000	0.7% 7 in 1000
More women got invasive uterine cancer (0.6% more)	0.3% 3 in 1000	0.9% 9 in 1000
No difference in having a stroke	About 0.4% in both groups 4 in 1000	
<i>Symptom side effects</i>		
More women had hot flashes (12% more)	68% 680 in 1000	80% 800 in 1000
More women had vaginal discharge (20% more)	35% 350 in 1000	55% 550 in 1000
More women had cataracts needing surgery (1.1% more)	2.0% 20 in 1000	3.1% 31 in 1000
Other things to know		
No difference in dying (from anything)	About 1% in both groups 10 in 1000	

How long has the drug been in use?

Nolvadex was first approved by the FDA in 1982 - Studies show that most serious side effects or recalls of new drugs happen during their first 5 years of approval.