

Drug Facts: NOLVADEX (tamoxifen) for preventing cancer

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	One other medicine (raloxifene) is approved to reduce the chance of breast cancer 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 (1.6% fewer due to the drug)	3.3%	1.7%
Dying from breast cancer was about the same	About 0.09% in both groups less than 1 in 1000	
Did NOLVADEX have side effects?		
<i>Life threatening side effects</i>		
More women had a blood clot in their leg or lungs (0.5% more due to the drug)	0.5%	1.0%
More women got invasive uterine cancer (0.6% more due to the drug)	0.5%	1.1%
Having a stroke was about the same	About 0.4% in both groups 4 in 1000	
<i>Symptom side effects</i>		
More women had hot flashes (12% more due to the drug)	69%	81%
More women had vaginal discharge (20% more due to the drug)	35%	55%
More women had cataracts needing surgery (0.8% more due to the drug)	1.5%	2.3%
Other things to know		
Dying for any reason was about the same	About 1.2% in both groups	

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.