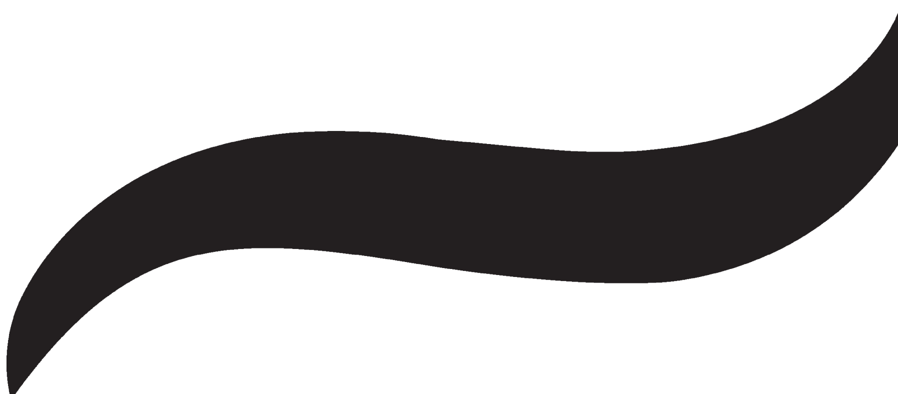
Postmenopausal women at high family history risk of breast cancer

Information for patients
Breast Care



This leaflet is for women who have been told that they have a high risk of breast cancer because of their family history and wish to discuss the use of Tamoxifen or aromatase inhibitors such as Anastrozole to decrease their risk.

Having a high risk of developing breast cancer means a lifetime risk which is 1 in 3 (approximately 30%) or higher as assessed by a genetic clinic.

Breast cancer risk

Breast cancer risk means the chance of developing breast cancer in the future. Everyone has a chance of developing breast cancer but this risk is increased if you have a family history of the disease. If you have an increased risk of developing breast cancer there are a number of options available to you. This includes screening to detect cancer early using mammography and/or MRI (magnetic resonance imaging). The other option is to try to decrease the risk of breast cancer. This can be done using tablets, termed chemoprevention. This leaflet discusses the use of a tablet to decrease breast cancer risk.

CHEMOPREVENTION AND BREAST CANCER RISK

Guidelines produced by the National Institute for Health and Care Excellence (NICE) for familial breast cancer recommend that women at an increased risk of breast cancer because of a family history of breast cancer, should be offered medication to reduce their risk. Options for breast cancer prevention in postmenopausal women at high risk include the drugs Tamoxifen and Anastrozole. All the tablets that have been shown to decrease breast cancer risk have an effect on oestrogen. Oestrogen is a natural female hormone which is produced mainly by the ovaries in women before menopause. It is important for the functioning of the reproductive system.

After menopause, the ovaries stop producing oestrogen, but low levels of the hormone continue to be produced in fat, liver, muscle and breast tissue. Many breast cancers rely on oestrogen to grow. These cancers are known as oestrogen-receptor positive (ER-positive) breast cancers. These cancer cells have proteins called receptors, to which the oestrogen attaches. When oestrogen comes into contact with the receptors, it fits into them and stimulates the cancer cells to divide so that the tumour grows. If the receptor or the hormone itself is blocked, the cancer cells may grow more slowly or die. Cancers not sensitive to oestrogen are called oestrogen-receptor negative (ER-negative), and the tablets have not been shown to have an effect on these cancers.

Am I menopausal?

Sometimes this can be difficult to determine but most women are thought to be menopausal if they have naturally stopped their periods for more than 12 months. A blood test to check hormone levels may be helpful in some cases before deciding whether Anastrozole would be an appropriate treatment. Tamoxifen can be used for prevention before and after the menopause.

Anastrozole

What is Anastrozole and how does it work?

Anastrozole is an aromatase inhibitor; it reduces the level of the hormone oestrogen in the body by blocking an enzyme. It is used to treat breast cancer by reducing the risk of recurrence in women with cancers that are oestrogen receptor positive.

Studies such as IBIS-II have shown it can also reduce the risk of developing an oestrogen sensitive breast cancer in postmenopausal women at high risk by approximately 50%. Anastrozole is usually prescribed as a tablet you take once a day by mouth.

For breast cancer risk reduction, studies suggest it needs to be taken for 5 years. It is currently unlicensed for this use in the UK though your GP may be happy to prescribe it for you based on study evidence and a recommendation from the breast clinic you are attending for surveillance.

Who is it for?

Anastrozole may be used to decrease the risk of breast cancer in post-menopausal women who are considered to have a high risk; unless they have severe osteoporosis. The evidence for the benefit of drugs like Anastrozole taken by women with a known gene change in BRCA1 or BRCA2 who have a very high risk of breast cancer is limited. This is because not many women with a BRCA1/2 gene change were included in the studies.

Who should not take Anastrozole?

Anastrozole is not recommended for women who have not reached their menopause (pre-menopausal). Women who have osteoporosis should not take Anastrozole; it does not improve bone density and may increase the risk of fracture.

Women should not take HRT or Tamoxifen at the same time as Anastrozole. Not all women at increased risk will decide to take Anastrozole. The potential benefits and side-effects should be considered and discussed with your doctor.

Possible side-effects

Anastrozole, like many medications, may cause unwanted side-effects. These side-effects may be worse for some than for others, as each person's reaction to any medicine is different. Some people have very few side-effects, while others may experience more. If you have side-effects you should discuss these with your GP.

Reported side effects include:

❖ Hot flushes

❖ Joint aches and/or stiffness

❖ Vaginal dryness

Anastrozole has not been shown to make a difference to your chance of getting a blood clot, or of developing cancer of the womb (see side effects for Tamoxifen).

TAMOXIFEN

What is Tamoxifen and how does it work?

Tamoxifen is a drug which blocks the action of oestrogen (it is sometimes called an anti-oestrogen drug), and has been used in the treatment of breast cancer for many years. There is now evidence that it can also help to prevent breast cancer occurring. Four large studies have explored the use of Tamoxifen in women at increased risk of breast cancer and have shown that it decreases the risk by about 40%. Tamoxifen is usually prescribed as a tablet you take once a day by mouth. For breast cancer risk reduction, studies suggest it needs to be taken for 5 years. Tamoxifen is now licensed in the UK for use in prevention. Tamoxifen reduces the effects of oestrogen in most areas of the body, including the breast. However, in the uterus, Tamoxifen acts like an oestrogen and encourages the growth of the lining of the uterus.

Using Tamoxifen to prevent breast cancer

There have been a number of studies researching the use of Tamoxifen to prevent breast cancer in women at increased risk. The IBIS-1 trial, which was carried out here in the UK, involved women with a family history of breast cancer, taking Tamoxifen or a placebo (inactive pill) for 5 years.

The actual number of breast cancers they developed during the 5 years, and after was then compared. At the 5 year point, the number of cancers had been reduced in women taking the Tamoxifen, but the complication (side-effect) rate was increased. At the 10 year point, the reduction in risk of breast cancer was 38%, and the benefit of Tamoxifen outweighed the complications which stopped after the tablet was stopped at 5 years.

Who is it for?

Tamoxifen can be used to reduce the risk of breast cancer in women with an increased risk, whether or not they have gone through menopause. The best age to start taking Tamoxifen is not known. It will vary between women depending on their level of risk. All of the research studies using Tamoxifen started from 35 years of age, or older. The evidence for the benefit of Tamoxifen taken by women with a known gene change in BRCA1 or BRCA2 who have a very high risk of breast cancer is limited. This is because not many women with a BRCA1/2 gene change were included in the studies. The evidence suggests that whilst it may be useful in BRCA2 gene carriers, the benefit for BRCA1 carriers is less certain.

Who should not take Tamoxifen?

Women who have a personal or family history of blood clots e.g. deep vein thrombosis (DVT) should let their doctor know as Tamoxifen may not be suitable. Women who have had cancer of the womb should not take Tamoxifen for chemoprevention. Women should not take HRT at the same time as Tamoxifen.

Not all women at increased risk will decide to take Tamoxifen.

The potential benefits and side-effects should be considered and discussed with your doctor.

Possible side-effects

Tamoxifen, like many medications, may cause unwanted side-effects. Often, Tamoxifen causes symptoms similar to the menopause. These side-effects may be worse for some than for others, as each person’s reaction to any medicine is different. Some people have very few side-effects, while others may experience more. If you have side-effects you should discuss these with your GP. Very rarely, if the side-effects are severe, you may have to stop taking Tamoxifen.

Common side-effects:

- ❖ Hot flushes and sweats
- ❖ Feeling sick (nausea): Although nausea is quite common initially, it usually improves after a few weeks
- ❖ Gynaecological problems (vaginal discharge, itching or dryness): Any vaginal bleeding after the menopause should be reported to your GP
- ❖ Leg cramps : If your leg becomes red, hot or swollen, tell your doctor immediately

Less common side-effects:

- ❖ Headaches - Blood clots (thrombosis): The risk of blood clots doubles whilst a woman takes Tamoxifen, but returns to usual population level once tablets are stopped. Women should stop Tamoxifen 6 weeks before any planned surgery.
- ❖ Cancer of the womb: Tamoxifen has been associated with an increased risk of cancer of the womb, approximately 3 extra women out of every 1000 will develop a uterine cancer if they take Tamoxifen for 5 years.
- ❖ Vision problems
- ❖ Voice changes

Effects of other drugs on taking Tamoxifen There is some research that suggests some drugs – including the antidepressants Paroxetine (Seroxat®) and Fluoxetine (Prozac®) – may cause Tamoxifen to be less effective, but this isn't certain. Tell your doctors about any other medicines you are taking so that they can check whether it is safe for you to use them alongside Tamoxifen.

Anastrozole versus Tamoxifen

For postmenopausal women, Anastrozole has been shown to reduce the risk of breast cancer more significantly, in a small number of studies. It has not been shown to affect the risk of blood clots or cancer of the womb.

For all chemoprevention drugs, it is not recommended to continue taking them for more than 5 years and they are not recommended for women who have no personal family history of breast cancer.

What should I do next?

If you have previously had your risk of breast cancer assessed and you fall into the high risk category, and wish to consider taking Anastrozole or Tamoxifen, you should talk to your GP or breast clinic about this. Your health care professional can talk you through your options for chemoprevention, if appropriate. Decisions aids to help women, along with a healthcare professional, make a more informed choice about which tablet if any, is right for them are available at: https://www.nice.org.uk/guidance/cg164/resources/

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Leaflet compiled with thanks to The Cancer Genetics Group and NICE

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Pub. date:	March 2022
Review date:	March 2024
Issue No:	01
Department:	Breast Care
Clinical lead:	K. McBain

PIL.PSTMEN.22_03673.L

Design - Medical Illustration, NHS Lanarkshire