Chemoprevention and inherited breast cancer risk reduction

A guide for women with a high risk family history

WHAT IS CHEMOPREVENTION?

Chemoprevention describes drugs that are used to reduce the risk of cancer developing. This is different from chemotherapy which describes drugs that are used in the treatment of cancer. Health Improvement Scotland (HIS) guidelines on Familial Breast Cancer published in June 2014 recommend two drugs which can be considered for use: Tamoxifen and raloxifene. Both these drugs have anti-oestrogen properties and are also known as SERMS (Selective oestrogen receptor modulators). Tamoxifen can be given to both pre and post-menopausal women, and Raloxifene to post-menopausal women only.

HOW DO SERMS WORK?

Many breast cancers rely on the female sex hormone oestrogen to grow. These cancers are known as oestrogen-receptor positive (ER-positive) breast cancer. SERMS block the effect of oestrogen on the breast tissue. This means the cancer either grows more slowly or stops growing altogether. SERMS have been used for many years in the treatment of women with breast cancer.

WHY HAVE I BEEN GIVEN THIS LEAFLET?

Evaluation of your family history has shown that you are at a high risk of developing breast cancer. Guidance from HIS recommended that chemoprevention should be considered in women at this level of risk.

ARE TAMOXIFEN AND RALOXIFENE LICENSED IN THE UK TO REDUCE BREAST CANCER RISK?

No. Both drugs are not currently approved in Europe for this purpose. However, there is evidence to support the use of these drugs as chemoprevention although is this not the primary indication for use. On the basis of the HIS recommendation the drugs can be prescribed for this purpose.

WHAT ARE THE POTENTIAL BENEFITS OF CHEMOPREVENTION?

Studies have demonstrated that chemoprevention reduces the risk of breast cancer developing by approximately 30% in women at high risk of developing breast cancer.

On average, if 1000 women at high risk of developing breast cancer DO NOT take tamoxifen, over a 10 year period

- about 100 women will develop breast cancer
- about 900 women will not.

On average, if 1000 women at high risk of developing breast cancer TAKE tamoxifen, over a 10 year period

- about 70 women (30 fewer) will develop breast cancer
- about 930 women will not.

It is expected that the benefits will continue after the drug is stopped, but this has not yet been proven.

The aim of chemo prevention is to reduce the risk of cancer developing; it has not been shown to reduce the risk of breast cancer related deaths.

DOES CHEMOPREVENTION REDUCE THE RISK OF ALL BREAST CANCERS?

No. Chemoprevention has been shown to reduce the risk of developing oestrogen-receptor positive breast cancer, but not oestrogen-receptor negative breast cancer. As a significant proportion of breast cancer in BRCA1 carriers is oestrogen-receptor negative, chemoprevention may not be as effective in these women.

ARE THERE ANY SIDE EFFECTS OF CHEMOPREVENTION?

Yes. There are both major and minor side effects to consider. These need to be considered alongside the potential benefits of chemoprevention.

WHAT ARE THE MAJOR SIDE EFFECTS OF CHEMOPREVENTION?

Tamoxifen is associated with a small increased risk of cancer of the womb (endometrial cancer). Both drugs are associated with a small increased risk of blood clots (venous thromboembolism).

- For every 1,000 women treated, tamoxifen would cause 6 endometrial cancers.
- For every 1,000 women treated, tamoxifen would cause 5 thromboembolic events.

WHAT ARE THE MINOR SIDE EFFECTS OF CHEMOPREVENTION?

Common side effects include menopausal symptoms such as hot flushes and vaginal discharge or dryness. Some patients can experience mild nausea, weight gain, and muscle and joint pains. Many women find that the side effects of chemoprevention are significant enough to stop taking the medication. Studies report that about 1 in 5 women will stop taking chemoprevention due to side effects.

ARE THERE ANY MEDICAL REASONS WHY I SHOULD NOT TAKE CHEMOPREVENTION?

If you have a personal or family history of blood clots or a family history of womb cancer you should not take tamoxifen. You should also not take tamoxifen or raloxifene if you are on HRT (Hormone Replacement Therapy) or the contraceptive pill or if you are trying to conceive. Tamoxifen or raloxifene can also interfere with the action of other drugs (such as antidepressants), so it is important for the prescribing Doctor to know your drug history.

AT WHAT AGE CAN CHEMOPREVENTION BE STARTED AND HOW LONG CAN IT BE TAKEN?

It is recommended that chemoprevention is taken for a maximum of 5 years and not started prior to age 35.

HOW DO I DECIDE IF I WANT TO TAKE CHEMOPREVENTION TO REDUCE MY RISK OF BREAST CANCER?

The decision is ultimately a personal one and both the potential benefits and potential risks need to be taken into careful consideration. You can arrange an appointment with the breast care nurse to go over all of this information and ask any questions you may have by completing and returning the attached form.

IF I DECIDE I WANT TO TAKE CHEMOPREVENTION WHO WILL PRESCRIBE IT TO ME?

We would recommend that tamoxifen or raloxifene is prescribed by your GP, who will be approached to provide repeat prescriptions and monitor for side effects.

SHOULD I STILL HAVE BREAST SCREENING IF I TAKE CHEMOPREVENTION?

Yes. You will have been advised what breast screening you are eligible for. This screening should be continued even if chemoprevention is taken.

Chemo prevention
Appointment request form

On the basis of your genetic risk of developing breast cancer you are eligible to consider the option of Tamoxifen and an information leaflet has been provided.

There are a number of medical conditions and situations (listed below) in which tamoxifen treatment is contraindicated (not suitable). If none of these apply to you and you would like to consider taking Tamoxifen, please complete and return this reply slip to request an appointment.

Tamoxifen is NOT suitable for patients with any of the following:

	YES	NO
Patients with/or a family history of blood clots (deep vein thrombosis or pulmonary embolism)		
A history or a family history of stroke or mini-stroke (transient ischemic attacks / cerebral vascular accidents)		
Medical conditions that increase risk of blood clots e.g. • Uncontrolled abnormal heartbeat *(atrial fibrillation)* • Uncontrolled diabetes • Uncontrolled high blood pressure *(hypertension)*		
Have had or have an increased risk of uterine *(endometrial)* cancer		
Morbid obesity or Body Mass Index (BMI) >35		
Patient who are or suspect they are pregnant		
Patients actively trying to conceive (or within 2 months of trying to conceive)		
Patients currently breast feeding		
Patients who have undergone bilateral mastectomy		

The information I have supplied is accurate and up to date to the best of my knowledge, I would like an appointment to discuss tamoxifen.

Name (please print): **Date:**

Signature:

Telephone Number:

Please return to: **FAO: Chemo prevention clinic**
Ardmillan House
42 Ardmillan Terrace
Edinburgh
EH11 2JL

Patient Label