Information about the treatment of breast cancer
Breast cancer
To be diagnosed with cancer naturally gives rise to many questions. This leaflet is for women with breast cancer who would like to know more about the disease and about treatment with Arimidex, and for their families.

Arimidex is a medicine that can be used for the treatment of hormone dependant breast cancer in post-menopausal women.

Arimidex can also be used to treat breast cancer that has spread to other parts of the body (metastasized) in post-menopausal women.

Arimidex is used worldwide for the treatment of breast cancer.

The purpose of this patient information leaflet is to make it easier to understand how Arimidex works and how it functions in the body. The following pages also contain facts about breast cancer and about organisations you can contact for further information, referral to support groups and help in many other ways.

A diagnosis of breast cancer can, initially, be overwhelming
To be told that you have breast cancer can, initially, be overwhelming and you will have many questions. In this patient information leaflet, medical terms are shown in *italics*. The terms are explained at the end of the leaflet.

*What is cancer?*
There are several different forms of cancer. In all of them cells become unstable and grow out of control. The cancer cells usually clump together and become what is called a *tumour* or a lump. Cancer tumours are also called *malignant* (harmful). Not all tumours are cancerous. Tumours which are not made up of malignant cells are called *benign* (not cancer). Benign cells do not spread to other organs.

Malignant tumour cells can break away from the tumour and be transported through the blood circulation system or the lymphatic vessels to other organs. A tumour that has spread in this way is called a *metastasis* (daughter tumour).

*Types of cancer*
Cancer is usually named after the organ in which it makes its *debut* (starts to develop). Accordingly, breast cancer first appears in breast tissue. If it spreads to, for example, the lungs, it will still be breast cancer, not lung cancer.

*The anatomy of the breast*
The breast is composed of *lobes* (mammary glands), milk ducts, fatty tissue, blood vessels and lymphatic vessels. The lobes contain glands that produce breast milk in nursing mothers; milk ducts connect the lobes to the nipple. The lobes and milk ducts are surrounded by fat. Lymph is transported along the lymphatic vessels to the lymph nodes that are situated in the armpit, above the collar-bone and in the breast. There are lymph nodes throughout the body.
Breast cancer – classification into stages
Breast cancer is usually classified according to different stages of development. In an early stage of the disease the tumour can be classified as 0, I or II. In an advanced (spread/metastasized) stage it may be classified as III or IV.

Stage 0 means that cancer cells have been found in a lobe or milk duct, but have not spread to the surrounding fatty tissue.

At stages I and II the cancer has spread from the lobes or milk ducts to the surrounding breast tissue, at stage II it may even have spread to the lymph nodes in the armpit.

Stadium III stands for local advanced breast cancer. The tumour may be larger than five centimetres in diameter and may have spread to lymph nodes or other tissue near the breast.

At stage IV the tumour has metastasized (produced daughter cells). The cancer has spread from the breast and lymph nodes in the armpit to other parts of the body.

Questions and answers
When is Arimidex used?
Arimidex is a medicine that can be used to treat hormone dependant breast cancer in post-menopausal women. A hormone dependant tumour is a tumour that needs the hormone oestrogen in order to grow.

When breast cancer has been diagnosed, the patient may have received both surgical and so called adjuvant (supportive) treatment. Adjuvant treatment may include:

- cytostatic therapy (cell poison, chemotherapy)
- endocrine therapy (hormonal therapy)
- radiotherapy

The treatment each patient receives depends on a number of different things, for example her general condition, if the tumour is hormone dependant and if the cancer has spread to other organs.

Arimidex is the first medicine in its class. It is used in post-menopausal women, either as adjuvant treatment for early breast cancer (stages I and II), or for the treatment of advanced (stage III-IV) breast cancer.

Arimidex has been shown to help many post-menopausal women with hormone dependant breast cancer. In a very large study of early breast cancer, Arimidex was shown to be effective and the risk of a relapse was diminished in women given Arimidex compared to those who received tamoxifen (1). In pharmaceutical studies of women with hormone dependant metastasized breast cancer, it could be shown that Arimidex prolongs the length of time before the cancer cells enter into a period of growth (2).

Arimidex can also be used for the treatment of metastasized breast cancer when other endocrine medicines, for example tamoxifen, not longer have sufficient effect.

Should Arimidex be used to treat my breast cancer?
The decision as to whether you are suitable for treatment with Arimidex is taken together with your doctor.
Arimidex is used as a supportive treatment in the early stage of hormone dependant breast cancer in post-menopausal women. Arimidex is also used to treat metastasized breast cancer in post-menopausal women.

Arimidex can be an alternative to anti-oestrogen treatment with tamoxifen, if this causes unpleasant symptoms similar to those experienced during menopause, for example hot flushes (1).

Now let’s back up a little bit, and try to answer some basic questions.

What is menopause?
Menopause is when a woman permanently stops menstruating. This usually happens when she is 40 to 50 years of age. During menopause activity in the ovaries decreases and they gradually stop producing the hormone oestrogen. The ovaries are situated in the abdomen and produce egg cells (ovum), oestrogen, which is secreted into the blood circulatory system, and the pregnancy hormone progesterone.

Methods of treatment that can be used to bring on menopause
Menopause can be induced in the following ways:
• by supplying GNRH agonists (e.g., goserelin, Zoladex) which obstruct the ovaries’ production of eggs
• by radiation of the ovaries
• by removing the ovaries surgically
• by the use of cytostatic agents

What role do hormones play in breast cancer?
Hormones, such as oestrogen, influence many of the body’s functions.

Oestrogen influences the development of breast tissue, indeed of the breast itself. Lactation (the production of milk) after a pregnancy is regulated by hormones.

Hormones, for example oestrogen and progesterone, are produced in the ovaries and transported through the blood circulatory system to the breast glands. In order for the hormones to be effective in the cells of the breast glands, the cells must have a structure into which the hormones can fit – like a key in a lock.

These cell structures are called receptors. All hormones have their own special receptors. When it comes to cancer cells in early breast cancer with a positive prognosis the hormone receptors are usually intact. The breast cancer is hormone dependant and is known as hormone receptor positive breast cancer. Oestrogen accelerates the growth of cancer cells in this form of breast cancer.

An important part of the treatment of breast cancer is, therefore, to block the effect of oestrogen. In breast cancer with a negative prognosis, the disease has changed the structure of the cancer cells so that they no longer have hormone receptors.

Tumours are, therefore, now examined with regard to the content of hormone receptors.
Can a post-menopausal woman still have oestrogen in her body?
Menstruation ceases when a woman reaches menopause. In a woman who is still menstruating, most of the oestrogen comes from the ovaries. The body can, however, produce oestrogen in another way. The adrenal glands, which are situated above the kidneys, produce androgens, male sex hormones. Under the influence of the enzyme aromatase, androgens are converted into oestrogen. Aromatase is found in muscles, fat, the liver and also in breast tumours. This is why oestrogen can be found in a woman, even if she no longer menstruates.

How are hormones used for the treatment of breast cancer?
Hormone treatment stops the production of certain hormones in the body and the effect of hormones in cancer cells can be inhibited (restrained).

In breast cancer in post-menopausal women, two different kinds of hormone treatment are usually used: anti-oestrogen and aromatase inhibitors. GnRH-therapy can be used in women who have not yet reached menopause.

What is anti-oestrogen?
Anti-oestrogens lock onto (block) the oestrogen receptors in the breast cancer cells. The result is that the body’s own oestrogen cannot, as previously, influence the oestrogen receptors of the tumour cells. Even if the body produces oestrogen, it can be prevented from acce-lerating the growth of the tumour. The anti-oestrogen most commonly used is called Nolvadex (tamoxifen).

Do anti-oestrogens work in all patients?
The probability of anti-oestrogen treatment being effective is greatest if the tumours are oestrogen receptor positive. Analysis of tumour cells will show if a tumour is oestrogen receptor positive or negative.

What are aromatase inhibitors?
Aromatase inhibitors block the activity of the enzyme aromatase, which is necessary for the conversion of androgen into oestrogen in post-menopausal women.

Arimidex is an aromatase inhibitor. It works selectively (only the targeted hormone is affected), by inhibiting the production of oestrogen, thereby preventing oestrogen from stimulating the tumour cells.

Do aromatose inhibitors work in all patients?
As with anti-oestrogens, aromatase inhibitors are most effective in women with an oestrogen dependent cancer tumour. A prerequisite for treatment with aromatase inhibitors is that the patient is post-menopausal.

Is Arimidex a form of cytostatic treatment?
No, Arimidex is not a form of cytostatic treatment. Cytostatic agents primarily attack cancer cells that are in a period of growth. The disadvantage of cytostatic agents is that even cells that grow and multi-
ply normally, for example hair cells and the cells of mucous membranes, are affected.

Arimidex works instead by blocking only aromatas, the enzyme necessary for the conversion of androgens to oestrogen in post-menopausal women.

**Is hormone substitution the same as hormone treatment?**
No. There are different purposes for these two forms of treatment.

Hormone substitution is used to try to compensate failing oestrogen production in the ovaries of menopausal women, in order to alleviate the symptoms of menopause.

Hormone therapy is used in the treatment of breast cancer, to inhibit the effects of oestrogen or to reduce the amount of oestrogen produced. The aim is to prevent oestrogen from stimulating the growth of tumour tissue.

**Which medicines are suitable for advanced breast cancer?**
Both anti-oestrogens and aromatase inhibitors play an important part in the treatment of advanced breast cancer. Cytostatic agents can also be used. You should talk to your doctor about whether Arimidex is suitable for you.

**What are the side effects of Arimidex?**
Generally Arimidex is well tolerated. The most usual side effects are heat rushes, nausea, aching in muscles and joints, head aches and fatigue.

**How do I take Arimidex?**
Arimidex is a tablet that is taken orally.
Dosing is easy – one tablet once a day.

**What should I ask my doctor about?**
Your doctor is well informed and has a great deal of knowledge about breast cancer and its treatment. Talk with him/her about the alternative treatments that are available. The more you know, the easier it will be for you to make decisions about, and take part in, your treatment. Here are some questions you might want to ask:

– Which stage has my breast cancer reached?
– Is my cancer oestrogen dependant?
– What alternative treatments are available to me?
– How can I know if Arimidex is effective in my case?
– What are the advantages of Arimidex compared to other treatments for breast cancer?
– What side effects can be caused by the medicine?
– How can I manage side effects that do occur?
– What side effects should I inform my doctor about?
– For how long should I take Arimidex?
– How will treatment be followed up?
It is important that you inform your doctor about any other medicines you take. Take care to include everything, including for example, vitamins, naturopathic preparations, homoeopathic preparations and pain killers.

Help yourself and accept help from others
If possible, keep living as normal.
If you have access to the Internet you can find more useful information about breast cancer (see the addresses to the right of this text). If you don’t have access to the Internet you can contact your local library.
Many patients feel the need to talk to other women who have breast cancer. Support groups can be a way of deepening your knowledge. You can also contact BRO – The National Organisation of Breast Cancer Associations (Bröstcancerföreningarnas Riksförbundet), see the address to the right.
People who work in patient organisations can also help you by assisting you and your family if problems arise. Staff at the hospital (your doctor, nurses etc.) or at a local cancer association, can refer you to a suitable support group.

Where can I find more information?
The insert, which comes with the medicine, contains information about storage etc.

Web sites
www.cancer.nu
On this site you will find answers to questions about breast cancer and prostate cancer. You can also order easy instruction cards that show you how to examine your breasts yourself.
www.fass.se
A home page with information about medicines available in Sweden.
www.bro.org.se
www.cancersamtal.nu
Meeting place and cancer discussion forum.

Web sites in English
www.cancer.org
American Cancer Society
www.y-me.org
Y-ME National Breast Cancer Organization
www.cancercare.org
Cancer Care
www.cancernet.nci.nih.gov
National Cancer Institute’s Cancer Information Service
www.breastcancer.org
Glossary

**ADJUVANT TREATMENT, ADJUVANT** – Supportive treatment given after breast cancer surgery, to eliminate any remaining cancer cells.

**ADRENAL GLANDS** – Glands situated above the kidneys that produce hormones, such as androgens, cortisol and aldosterone.

**ADVANCED** – A cancer which has progressed and spread to other parts of the body.

**ANDROGENS, MALE SEX HORMONES** – Hormones produced in the adrenal glands, that under the influence of the enzyme aromatase are converted into oestrogen.

**ANTI-OESTROGEN** – A medicine which inhibits oestrogen and which is used to treat breast cancers that depend on oestrogen for growth.

**AROMATASE** – The enzyme which converts androgen to oestrogen.

**AROMATASE INHIBITOR** – A medicine which prevents the enzyme aromatase from producing oestrogen.

**BENIGN** – Not cancerous. A benign tumour does not grow into surrounding tissue or spread to other parts of the body.

**BIOPSY** – A tissue sample that is examined under a microscope to check for the presence of cancer cells.

**CLINICAL STUDY** – A research study to evaluate a medicine’s safety and efficacy in humans.

**CYTOSTATIC TREATMENT, CHEMOTHERAPY** – Treatment with medicines that attack cancer cells.

**ENDOCRINE THERAPY** – Treatment given to diminish the tumour’s access to oestrogen.

**ENZYMES** – Proteins with the ability to speed up chemical reactions.

**GLAND** – A tissue which produces different substances. There are two main types; exocrine, e.g., the salivary glands, which secrete substances through a duct and endocrine, e.g. the adrenal glands, which secrete substances into the blood circulatory system.

**GnRH agonist** – A medicine which prevents hormone production in the sex glands of both men and women.

**HORMONES** – Substances which are produced by the body’s inner organs and which influence bodily functions.

**HORMONE RECEPTOR POSITIVE BREAST CANCER** – Breast cancer which needs female sex hormones in order to grow, and in which oestrogen receptors and/or progesterone receptors can be found.

**HORMONE SUBSTITUTION** – Drug therapy to replace deficient female sex hormones in post-menopausal women.

**HORMONAL THERAPY** – The treatment of breast cancer, in which hormone like medicines are used to inhibit the effects of oestrogen.
LOBES – Structures in the breast which produce milk in nursing mothers.

LOCALLY ADVANCED – A breast cancer that is growing and that measures 5 cm or more. It may have spread to neighbouring lymph nodes or other nearby tissues.

LYMPH – A liquid which transports tissue fluid along the lymphatic vessels. It contributes to the elimination of alien matter from the body and plays an important part in immune defence.

LYMPH NODES – Pea sized, gland like formations around the breast, in the armpit, above the collar-bone and inside the breast. Lymph nodes are also found in several other parts of the body. Lymph nodes are a part of the lymphatic system.

MALIGN – Cancerous. Cancer able to grow into surrounding tissues and spread to other parts of the body.

MENOPAUSE – The point in time when the functions of the ovaries gradually stop and menstruation ceases.

METASTASIS – A daughter tumour.

METASTASIZATION – The spread of a tumour from one organ to another.

OESTROGEN – A female sex hormone; one of the hormones that can hasten the growth of certain forms of breast cancer.

OESTROGEN DEPENDANT BREAST CANCER – Also called oestrogen receptor positive breast cancer. Tumours that depend on female sex hormones in order to grow.

OVARIES – Female organs of reproduction that produce egg cells and hormones.

POST-MENOPAUSAL – Following the final menstrual period.

PROGESTERONE – A female sex hormone.

PROGRESSIVE – Increasing in scope or severity.

RADIATION – Cancer treatment using different types of radiation (e.g., X-rays, gamma rays) to attack tumour cells.

RECEPTOR – Element of a cell that can identify and specifically bind one or more substances, e.g., hormones.

THE LYMPHATIC SYSTEM – Tissues and organs which produce and transport white blood cells, which fight infections. The system contains a network of lymphatic vessels (thin tubes) that transport lymph and white blood cells. The lymphatic vessels branch into all the tissues of the body.

TUMOUR – Abnormal tissue formations. They can be malignant (harmful cancerous tumours) or benign (non-cancerous tumours).

NAME OF THE MEDICINE: Arimidex tablet 1 mg
ACTIVE SUBSTANCE: Anastrozole 1 mg
INDICATION/AREA OF USE: Breast cancer
Adjuvant treatment of oestrogen receptor positive breast cancer in post-menopausal women.
Treatment of hormone dependent advanced breast cancer in post-menopausal women.
Anastrozole is not recommended for patients with oestrogen receptor negative tumours.
For further information see FASS for Patients (In Swedish only).

References
1. Lancet 2002, 359; 2131-2139
2. Cancer 2001, 92; 2247-58
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Referenser
1. Lancet 2002, 359; 2131-2139