

Patient Guide

Herceptin

For early breast cancer



PHARMAC
Pharmaceutical Management Agency

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Who is this booklet for?

This booklet is about a medicine called Herceptin, which is used to treat breast cancer.

This booklet is intended for women with early breast cancer who are thinking about taking Herceptin or are taking it already. It explains more about your treatment with Herceptin. It does not replace the advice given to you by your cancer specialist, nurse or other health professional.

This booklet does not tell you everything about breast cancer and its treatment. Page 11 tells you where to find more information.

Herceptin is also used to treat advanced (or metastatic) breast cancer. Talk to your cancer specialist, nurse or other health professional if you would like more information about using Herceptin to treat HER2-positive advanced breast cancer. Page 10 also tells you where to find more information.

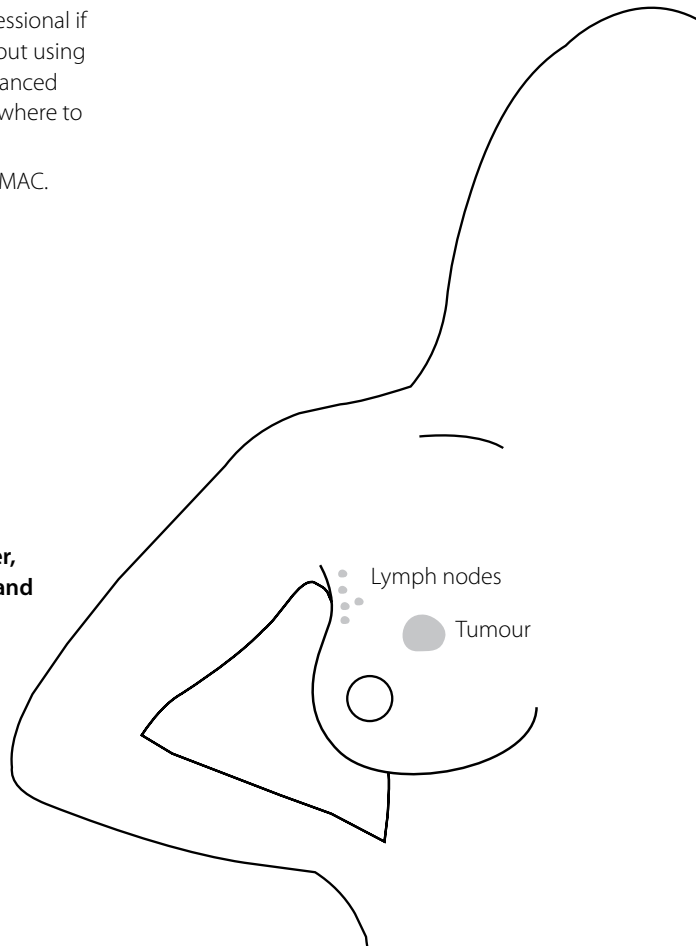
This booklet was produced by PHARMAC.

What is early breast cancer?

Breast cancer starts growing in the breast. Sometimes breast cancer spreads to other parts of the body. Breast cancer usually spreads to the lymph nodes in the armpit first. Breast cancer that is only in the breast or that has spread only as far as the armpit area is called *early breast cancer* (see the picture below).

Breast cancer that has spread further than the armpit area to other places near the breast, such as the skin or muscles in the chest, is called *locally advanced breast cancer*. Breast cancer that has spread to other parts of the body, such as the lungs, liver and bone, is called *advanced breast cancer* or *metastatic breast cancer*.

**Early breast cancer,
showing tumour and
lymph nodes**



What is Herceptin?

Herceptin is a medicine used to treat breast cancer. Herceptin is the brand name of the medicine. The active ingredient in Herceptin is called *trastuzumab* (pronounced 'trass-too-zoo-mab').

It is a type of medicine called a *monoclonal antibody*. Monoclonal antibodies target certain cells or proteins in the body.

Herceptin only works in a particular type of breast cancer. In this type of breast cancer, the breast cancer cells make too much of a protein called *HER2*. This sort of breast cancer is called *HER2-positive breast cancer*. In HER2-positive breast cancer, the extra HER2 protein that the cancer cells make causes the cancer to grow and spread more quickly. Herceptin attaches to this extra HER2 protein, slowing down the growth of the cancer cells by blocking the effect of the extra HER2 protein.

What is Herceptin used for?

Herceptin is used to treat HER2-positive early breast cancer and HER2-positive advanced (or metastatic) breast cancer. This booklet only talks about using Herceptin to treat HER2-positive early breast cancer.

In HER2-positive early breast cancer, Herceptin is used after surgery to reduce the chance of the cancer coming back. Women who take Herceptin also have treatment with other chemotherapy medicines and may also have treatment with radiation therapy.

Is Herceptin right for you?

There are a range of things to consider when you and your cancer specialist are thinking about whether Herceptin is right for you, such as:

- whether you have the type of breast cancer that Herceptin is used for
- what the possible benefits and risks of treatment with Herceptin are for you
- whether you have any heart problems that mean it might not be a good idea for you to take Herceptin.

Your personal choice is an important part of the decision. If you wish to find out more about other breast cancer treatments, you can find details of other places to go for information on page 10 of this booklet.

Do you have HER2-positive breast cancer?

Herceptin only works on HER2-positive breast cancer. A sample of breast cancer removed from your breast during surgery will be tested in a laboratory to see if it makes too much HER2 protein. About 1 in 4 women with breast cancer have HER2-positive breast cancer. Your cancer specialist will tell you if your breast cancer is HER2-positive.

Weigh up the benefits and the risks of taking Herceptin

If you have HER2-positive breast cancer, then treatment with Herceptin may help to reduce the chance that your breast cancer will return. However, like all medicines Herceptin can cause side effects. These can sometimes be serious.

Herceptin is quite a new medicine. As with all new medicines, there are still some things we don't know about it. We don't know what the best way to use it is and what effects it may have on your body many years after treatment. This is normal for new medicines but it means that there might be some benefits and risks of Herceptin that we do not know about yet.

You can read about what is known about how effective Herceptin is in the section called 'Does Herceptin work?' on page 7 of this booklet. You can read more about the risks and side effects of Herceptin in the section called 'What are the side effects of Herceptin?' on page 5.

Your cancer specialist will check your heart function

Before you start treatment with Herceptin, your cancer specialist will check to see whether your heart is working well. This is because Herceptin can affect the way your heart works. If you already have some heart problems, Herceptin may not be right for you. There is more information about the effect of Herceptin on the heart on page 6.

How is Herceptin taken?

Herceptin is given as an *intravenous infusion*, sometimes called a 'drip', into a vein in your hand, wrist or arm. You will need to visit a cancer treatment centre at a hospital to receive Herceptin.

The first infusion of Herceptin will take about 90 minutes. Each one after that will take about 30 minutes. You will need to stay at the treatment centre for a short time after each infusion in case you have any side effects that need treatment.

If you choose to have the government-funded Herceptin treatment you will need to visit the treatment centre to receive Herceptin once a week for nine weeks*. You will start taking a type of chemotherapy medicine called a *taxane* at the same time as you start Herceptin treatment. The taxane chemotherapy medicine you will have will be called docetaxel or paclitaxel. This is given once every 3 weeks, so you will receive it on every third visit to the treatment centre when you receive Herceptin.

Your cancer specialist will ask you to sign a consent form if you choose to have the government-funded treatment course of Herceptin. This is because using Herceptin at the same time as a taxane is not approved by Medsafe, the agency that regulates medicines in New Zealand, but it is approved to be used this way by regulatory agencies in some other countries. It is not unusual for cancer and other medicines to be used in a way that is not approved by Medsafe.

You will finish having treatment with Herceptin and taxane chemotherapy after 9 weeks. You may then start treatment with a combination of other chemotherapy medicines if you did not have other chemotherapy before you started treatment with Herceptin.

You may find it helpful to mark the days and times when you need to visit the treatment centre on the calendar provided in this pack.



* You may have Herceptin every 3 weeks rather than weekly, because some cancer treatment centres may choose to give Herceptin this way. Your cancer specialist can tell you more about this.

What are the side effects of Herceptin?

Every medicine has some side effects. Different people may experience different side effects from a medicine. Some people have no side effects at all. You may need medical treatment if you have side effects.

About half the women who take Herceptin experience side effects from it. These are most often fever or chills that happen during the Herceptin infusion or soon after the infusion has finished. Herceptin can sometimes cause serious side effects, such as allergic reactions or heart problems.

Your cancer specialist will carefully check your health before you are treated to make sure that you are healthy enough to take Herceptin. Your cancer nurse will be checking on you regularly during each Herceptin infusion and for a short time afterwards in case you have any side effects that need treatment. You will also see your cancer specialist regularly while you are having treatment with Herceptin. Talk to your cancer specialist or nurse if you feel unwell.

You will also be taking other medicines for cancer while you are taking Herceptin. You may experience side effects from these other medicines. Ask your cancer specialist or nurse about the possible side effects of these other medicines.

It is very important that you tell your cancer specialist and nurse if you are taking any other medicines, including any that you have got from a traditional healer, or bought from a pharmacy, supermarket or health food shop. This is because mixing some medicines can affect the way the medicines work or cause new side effects.

There is more information about some of the most common and most important side effects of Herceptin on this page and the next. This is not a complete list of all of the known side effects of Herceptin. See page 11 to find out

where you can get more information about the side effects of Herceptin.

Side effects related to the Herceptin infusion

Fever and chills

You may have fever (a high temperature) or chills while you are receiving a Herceptin infusion or soon after the infusion has finished. These are the most common side effects of Herceptin. You are most likely to have these side effects the first time you receive Herceptin. These side effects are unpleasant but they are not serious.

Other side effects

You may have other side effects while you are having an infusion, but these are less common than fever and chills. They include nausea, vomiting, shivering, a headache, pain in your stomach, back, chest or neck, weakness or soreness in your muscles or joints, feeling tired, dizziness, skin rashes and cough.

Tell your cancer specialist or nurse if you have fever or chills or anything else that makes you feel unwell during or after receiving Herceptin. They can give you medicines to help treat the side effects.

More serious side effects

It is extremely rare to have serious side effects from an infusion. Serious side effects include severe difficulty breathing, severe coughing, irregular beating of the heart and very low blood pressure. If you have serious side effects during the infusion, your cancer specialist will stop the infusion and may give you medicines to treat the side effects. Your cancer specialist will watch you closely until the side effects have stopped.

Serious side effects from the infusion usually happen during the infusion or within an hour or so after it has finished. In extremely rare cases serious side effects from the infusion have happened up to six hours after the infusion has finished. If you think you might be having

a serious side effect when you have returned home after the infusion, immediately contact your cancer specialist or visit your nearest Accident and Emergency.

Allergic reactions to Herceptin

It is possible to have an allergic reaction to Herceptin. This is extremely rare. The signs of an allergic reaction include a skin rash, itching, wheezing, swelling of the face, lips and tongue, and difficulty breathing. Tell your cancer specialist or nurse if you have any of these effects. Most allergic reactions happen during an infusion but in very rare cases they happen after an infusion has finished. If you are allergic to Herceptin, you will probably have a reaction during your first infusion.

If you have a severe allergic reaction to Herceptin, the infusion will be stopped. Your cancer specialist will give you medicines to treat the symptoms and will watch you closely until the reaction has stopped.

Heart problems with Herceptin

Herceptin can affect the way the heart works. It can cause the heart muscle to pump less strongly. Sometimes this doesn't cause any symptoms but sometimes it causes a condition called *heart failure*. This is not the same as a heart attack and does not mean that the heart stops.

The symptoms of heart failure are feeling short of breath and getting tired easily after light physical activity. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet. Heart failure is treated with medicines to help reduce the symptoms and stop them from getting worse.

In one clinical trial:

- 2 out of every 100 women who took Herceptin had heart failure symptoms
- 3 out of every 100 women who took Herceptin had a reduction in their heart function with no symptoms or mild symptoms.

Overall 4 out of every 100 women had to stop taking Herceptin because of heart problems.

Before you start taking Herceptin, your cancer specialist will check to see how well your heart is working to find out if it is strong enough for you to take Herceptin. He or she will ask you if you have ever had any heart or circulation problems, such as a heart attack or high blood pressure. Your cancer specialist may also organise for you to have tests (usually an *echocardiogram*) to measure how well your heart works.

Your cancer specialist may also organise for you to have your heart function tested while you are being treated with Herceptin. This is to check if Herceptin is affecting your heart.

If you start to have symptoms of heart failure (feeling short of breath and getting tired easily after light physical activity) then your cancer specialist may talk with you about whether you should keep taking Herceptin or not. The decision to keep taking Herceptin will depend on how severe the symptoms are, your general health and your personal choice.

We don't yet know what the long-term effects of Herceptin are on the heart. We don't know if stopping Herceptin makes the heart function go back to normal, but stopping Herceptin and treating the heart failure with other medicines seems to improve the symptoms.



Does Herceptin work?

Yes, treatment with Herceptin reduces the chance of HER2-positive early breast cancer coming back and may help women with HER2-positive early breast cancer to live for longer than they would have without it. However, not every woman will benefit from taking it. We do not know yet if Herceptin can cure breast cancer.

How has Herceptin been tested?

Herceptin has been tested in clinical trials which are studies that compare different treatments. Just over 11,000 women with early breast cancer have taken part in clinical trials of Herceptin around the world. Over 6000 of these women took Herceptin in addition to other chemotherapy treatments. The other 5000 women took just the other chemotherapy treatments without Herceptin.

These clinical trials have tested whether Herceptin stops early breast cancer coming back when it is used in addition to other treatments (surgery, radiation therapy and chemotherapy). They have also tested whether women treated with Herceptin live for longer than those not treated with it. So far clinical trials have only looked at the effects of Herceptin for a few (2-4) years after treatment.

Medical researchers have tried using Herceptin in many different ways. It has been tested when taken at the same time as other chemotherapy medicines, taken after other chemotherapy medicines, combined with different types of chemotherapy medicines and taken for different lengths of time.

We now know that Herceptin reduces the chance of early breast cancer coming back when it is used in a number of different ways. However, we don't yet know if giving it one way is any better than another, or if giving it for longer is any better than shorter treatment. More clinical trials are being done to find out more about how Herceptin can best be used.

The results of six clinical trials showing the effect of Herceptin on the chances of HER2- positive early breast cancer coming back are shown on the next page.

How much does Herceptin help?

Adding Herceptin to usual treatments (such as surgery, radiation therapy and chemotherapy) reduces the chance of HER2-positive early breast cancer coming back. However, the chance of HER2-positive cancer coming back is already much reduced by these usual treatments, so the extra benefit from taking Herceptin is small.

For example, in one clinical trial of Herceptin in early breast cancer, after 2 years:

- 87 out of every 100 women who took Herceptin were alive and their cancer had not come back
- 81 out of every 100 women who did not take Herceptin were alive and their cancer had not come back.

In other words, in the group who took Herceptin, an extra 6 out of 100 women were alive and their cancer had not come back compared with the group who did not take Herceptin. Most of the other clinical trials of Herceptin had similar results. The graph on page 7 shows the results of the clinical trials of Herceptin for early breast cancer that have been done so far.

These clinical trials used Herceptin in different ways, such as with different chemotherapy medicines, for different lengths of time and taken after (sequential) or at the same time (concurrent) as other chemotherapy medicines. It is not possible to work out from the information available at the moment which way is best to take Herceptin. However, in each trial, the benefit from using Herceptin in addition to other treatments was small and in two trials of 12 months Herceptin given after other chemotherapy there was no benefit.

We don't yet know much about the effect of Herceptin on the chance of eventually dying

from breast cancer, or if Herceptin can cure breast cancer completely. This is because Herceptin is quite a new medicine and has not been tested for long enough. One clinical trial found that women with HER2-positive early breast cancer who took Herceptin were more likely to be alive 2 years after starting treatment.

After 2 years:

- 97 out of every 100 women who took Herceptin were still alive
- 95 out of every 100 women who did not take Herceptin were still alive.

In the clinical trials that have been started so far, most women were still alive at least 3 years after treatment, so it will take much longer to find out for sure if Herceptin reduces the chance of eventually dying from HER-2 positive early breast cancer.

How sure can we be about the results for Herceptin?

In all clinical trials, there is the possibility that the results we see are just due to chance. The Herceptin trials all have a group consisting of patients who received Herceptin ('Herceptin' patient group), and a group consisting of patients who did not receive Herceptin ('control' patient group). If the disease outcomes for the Herceptin patient group are better than those for the control patient group, and this difference is unlikely to have occurred by chance, we say that Herceptin has had a 'statistically significant' effect.

All clinical trials have a level of precision around the results we see. 'Confidence intervals' show how precisely a trial can assess the true differences between treatment groups. Confidence intervals estimate the range of values where the true result of a trial will likely lie. Confidence intervals get larger as they become less precise and they get smaller as they become more precise. In general, larger trials provide more precision (i.e. they have smaller confidence intervals) than smaller trials, but once study results have shown statistical significance the trial size is less important.

The following graph shows how well Herceptin worked in the six clinical trials. It also shows the precision around the results. The dark pink area is the difference in disease free survival between the Herceptin patient group and the non-Herceptin patient group in each study. Disease free survival is when patients remain alive and free of breast cancer without it returning; so a difference in disease free survival shows how well Herceptin reduces disease coming back. This is the best estimate of how effective Herceptin is.

The bars in the graph show the confidence interval range (that is, precision) of results in each clinical trial. Where the confidence interval bar crosses into the light pink area, which happens

for two of the studies (2 and 3), the result is not statistically significant; in these studies Herceptin may have no benefit. The benefit of Herceptin was statistically significant in all of the other studies. Although more patients have been treated with 12 months Herceptin (5 trials) than 9 weeks (1 trial), the results for concurrent 9 week treatment are statistically significant.

This graph shows the results of the six clinical studies that have tested Herceptin treatment for HER2-positive early breast cancer. Study 1 is the HERA trial which examined sequential 12 months treatment, Study 2 is NCCTG-N9831 Arm B which examined sequential 12 months treatment, Study 3 is PACS04 which examined sequential 12 months treatment, Study 4 combines data from two separate trials NSABP-B31 and NCCTG-N9831 Arm C which examined concurrent 12 months treatment, Study 5 is BCIRG006 which examined concurrent 12 months treatment, and study 6 is FinHer which examined concurrent 9 weeks treatment. From the currently available data it is not possible to work out which is the best way to use Herceptin just by comparing the results of the different clinical trials on this graph, and more research is needed. However, the graph does show that Herceptin had a similar effect in most of the clinical trials, and that the benefit from using Herceptin in addition to other treatments is small. Herceptin was used in different ways in these trials — for different lengths of time, with different chemotherapy medicines, and either after or at the same time as other chemotherapy medicines. There was a different number of women in each trial, and each trial followed women for different lengths of time after treatment. References for the studies are on page 10; studies 2, 3 and 5 and the updated results for study 4 have not been formally published but data from these studies have been presented at international cancer meetings.

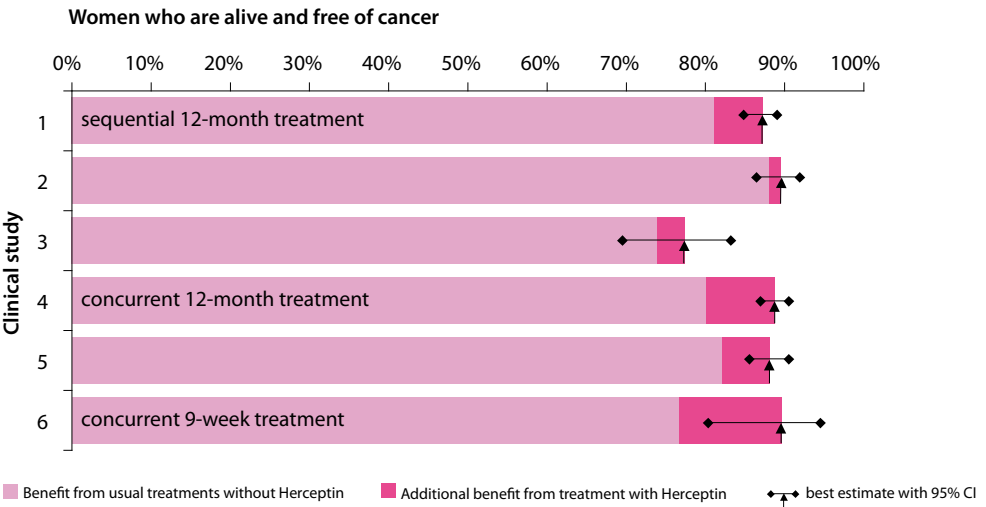
Combining results from the trials gives:

For sequential 12 month Herceptin (3 trials), the best estimate is that at 1.8 years follow-up there will be 4 fewer cancer recurrences for every 100 patients treated (i.e. a 4% improvement in disease free survival), but we can be 95% sure that the true result will lie somewhere between 3 and 6 for every 100 patients (3-6%). In other words, in these trials Herceptin treatment may improve disease free survival by as much as 6% or as little as 3% over that time, compared with no treatment.

For concurrent 12 month Herceptin (2 trials), the best estimate is that at 2.4 years follow-up there will be 7 fewer cancer recurrences for every 100 patients treated (i.e. a 7% improvement in disease free survival) but we can be 95% sure that the true result will lie somewhere between 6 and 8 for every 100 patients (6-8%).

For the funded 9 week concurrent treatment (1 trial), the best estimate is that at 3 years follow-up there will be 13 fewer cancer recurrences for every 100 patients treated (i.e. a 13% improvement in disease free survival) but we can be 95% sure that the true result will lie somewhere between 4 and 18 for every 100 patients (4-18%).

Results of the six Herceptin trials with confidence intervals



Talk to your doctor if you want more information about the importance of 'statistical significance' or 'confidence intervals' in understanding clinical trial results, as these are complex scientific terms that may need some explaining.

Will I have to pay for treatment with Herceptin?

District Health Boards (DHBs) will pay for treatment of HER2-positive early breast cancer with Herceptin.

If you have HER2-positive early breast cancer and Herceptin is suitable for you, your District Health Board will pay for you to have the concurrent 9-week treatment course with Herceptin. You will receive treatment with a chemotherapy medicine called a taxane at the same time as Herceptin. Your District Health Board will also pay for your taxane treatment. You will not have to pay anything for your treatment.

If you would like more information about how the decision was made to fund Herceptin for HER2-positive early breast cancer, read the booklet called 'Funding for Herceptin in early breast cancer'. You can find a copy inside your Herceptin patient kit or you can download it from the PHARMAC website (www.pharmac.govt.nz).

Other treatments for early breast cancer

There are many different treatments for early breast cancer. The types of treatment you have will depend on the features of the breast cancer, your general health and your personal choice.

Most women with early breast cancer first have surgery to remove the cancer, then one or more other treatments (such as radiation therapy, chemotherapy and hormone therapy) to destroy any cancer cells left in the body and reduce the chance of the cancer coming back.

Below there is a short description of each of the most common treatments for early breast cancer. If you would like more information about treatments for breast cancer, see page 10.

Surgery

Most women with early breast cancer have surgery to remove the cancer from the breast. Surgery may remove the cancer and a small amount of tissue around it (this is called a *lumpectomy* or *breast-conserving surgery* and is the most common type of surgery for early breast cancer) or it may remove the whole breast (a *mastectomy*).

Usually some lymph nodes are removed from the armpit during surgery. This is to test if the cancer has spread into the armpit area and to remove cancer that may have spread there.

Radiation therapy

It is common to have radiation therapy to destroy any cancer cells that may be left in your breast or chest wall after surgery. Radiation therapy means using x-rays to destroy cancer cells.

Radiation therapy only destroys cancer cells in the areas of the body that it is aimed at. Other treatments (such as chemotherapy, hormonal therapy and Herceptin) are used to destroy cancer cells that may have spread beyond the breast and armpit area but cannot be detected.

Chemotherapy

Chemotherapy may be used after surgery and radiation therapy. Chemotherapy uses medicines to destroy cancer cells that may be left in the breast and any that may have spread beyond the breast and armpit area but cannot be detected.

Hormonal therapies

Some breast cancers grow in response to the female hormone oestrogen. Hormonal therapies (such as tamoxifen, anastrozole, letrozole or

exemestane) help to destroy these sorts of cancers. They work by stopping the cancer cells from getting oestrogen or by stopping your body from making oestrogen.

Hormonal therapies help to destroy cancer cells that may be left in the breast, and any that may have spread beyond the breast and armpit area but which cannot be detected. They are usually recommended for women who have breast cancer cells with oestrogen receptors on them (called 'oestrogen-receptor-positive' or 'ER-positive' breast cancer). They can be given in addition to surgery, radiation therapy and chemotherapy.

Where to get more information and support

Talk to your cancer specialist, GP, nurse, Maori or Pacific health provider, pharmacist or other health professional if you have any questions about breast cancer or your treatment options. Listed below are some other places you can get more information and help.

For more information about Herceptin

Get a copy of the Consumer Medicine Information (CMI) for Herceptin. The CMI tells you things to be careful of while you are taking the medicine, most of the known side effects and who should not take the medicine. You can get a copy of the CMI from

- your cancer specialist or pharmacist
- Medsafe (go to www.medsafe.govt.nz)
- Roche, the company that makes Herceptin (Phone 0800 656 464).

For general information about breast cancer and breast cancer treatments

Find reliable information on the Internet. The Internet is a popular source of information about medical treatments, but beware because not all of the information on it is accurate or up-to-date. Below are some good websites from New Zealand and overseas that you might find useful.

- The Cancer Society of New Zealand (www.cancernz.org.nz): information sheets about living with cancer and a directory of cancer information resources available throughout New Zealand (www.cancernz.org.nz/Info/InfoCentre/).
- BestTreatments (www.besttreatments.co.uk): a website from the United Kingdom that gives reliable information about which treatments work for many different conditions. It contains detailed information about treatments for breast cancer. Access to BestTreatments is free for people in New Zealand.
- BreastHealth (www.breasthealth.com.au): a website from Australia with detailed and easy-to-read information about breast cancer and its treatment. You can download a copy of 'A guide for women with early breast cancer' (www.breasthealth.com.au/types/early.html) for detailed information about early breast cancer.



For information about help for women and their families

Find your local breast cancer support services. These include breast cancer support groups, workshops and counselling for women with breast cancer and their families. You can find out what services are available in your area by contacting your local division of the Cancer Society of New Zealand. You can find their contact details in the telephone book or by visiting www.cancernz.org.nz/Society/Divisions/.

Call the Cancer Information Helpline. You and your family can talk to an experienced nurse for information about cancer treatments, support services and information sources. You can call them on 0800 226 237 (toll free) between 8 am and 5 pm, Monday to Friday.



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