

Understanding your treatment

with Truqap and fulvestrant



This guide does not replace the Patient Information Leaflet (PIL) that is provided with this medicine.

For full information about your treatment, consult the PIL by scanning the QR code on the right.

Truqap in combination with fulvestrant is used to treat adult patients who have hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer that is advanced or that has spread to other parts of the body with one or more abnormal "PIK3CA", "AKT1" or "PTEN" genes and whose cancer is not responding to other anti-hormonal based therapies.

If you have any questions about your treatment, please talk to your cancer care team.



Reporting side effects

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/> or via the 'MHRA Yellow Card' app in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

Side effects can also be reported to AstraZeneca in the following ways:

Online: <https://contactazmedical.astrazeneca.com> | Email: Medical.InformationUK@astrazeneca.com | Telephone: 0800 783 0033

WELCOME TO YOUR TRUQAP SUPPORT GUIDE

Throughout your treatment for advanced breast cancer there can be a lot of information to take in, which can sometimes feel overwhelming.

This guide is here to help. It has been developed to help you understand your advanced breast cancer treatment, Truqap (*TROO-Cap*), also known as capivasertib (*ca-pee-va-ser-tib*). It also includes steps you can take to manage your treatment.

While this guide is designed to support you through your treatment, it is important that you also read the Patient Information Leaflet (PIL) before you start taking Truqap.



Remember that your cancer care team is always there for you if you have any concerns or questions about your treatment.

What this guide includes:

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UNDERSTANDING YOUR TREATMENT

Breast cancer can advance and spread into the surrounding areas and other parts of the body. This is called advanced breast cancer.

Your doctor will have carried out several tests to help find out what type of advanced breast cancer you have. This is really important to help you and your doctor decide what treatment may work best for you.

Your type of breast cancer is HR+/HER2-, and you have changes in one or more of your PIK3CA, AKT1 and/or PTEN genes.

WHAT DOES THIS MEAN?

This means there are two reasons why your breast cancer is growing:

- 1 Changes in your **PIK3CA**, **AKT1** and/or **PTEN** genes are helping your breast cancer cells to grow.
 - It can help to think about genes as the instruction manual for our cells. They guide how cells grow, develop and function. But when cancer interferes with these instructions, cells may start behaving abnormally, leading to uncontrolled growth and spread of cancer
- 2 Your breast cancer is sensitive to hormones like oestrogen – this is known as being hormone receptor positive (**HR+**).
 - In breast cancer, hormones such as oestrogen can encourage breast cancer cells to grow. Hormone receptors are like the lock and the key is a hormone, like oestrogen. When hormones turn the lock, this encourages the cancer cells to grow

Your type of breast cancer is negative for human epidermal growth factor receptor 2 (**HER2-**).

HER2 is a protein found on the surface of cancer cells. Some people with breast cancer have too much HER2 on the surface of their cancer cells, which makes them grow. This is known as HER2-positive breast cancer (HER2+). Other people with breast cancer, like you, do not have a large amount of HER2 and so are known as HER2-negative.

WHAT DOES THIS MEAN FOR MY TREATMENT?

You have been prescribed two treatments to target the different reasons your breast cancer is growing. This is known as targeted therapy.

- 1 Truqap works by blocking the effects of proteins called AKT kinases. These proteins help cancer cells to grow and multiply. By blocking their action, Truqap can reduce growth and spread of the cancer and help to destroy cancer cells.
- 2 Fulvestrant works by fitting into the locks on your cancer cells (the hormone receptors), binding to them and stopping them working. This means that hormones can't 'turn the lock' and tell your cancer cells to grow.

Truqap and fulvestrant work together to slow down the progression of breast cancer.



HOW TO TAKE YOUR TREATMENT

Truqap is taken in combination with fulvestrant. They're each taken in different ways, and it's really important for your treatment that you take both drugs exactly as prescribed.

This helps them to work as they should to treat your breast cancer.

On the next page is an outline of a standard treatment plan, which your cancer care team may recommend.

Always take your treatment exactly as your cancer care team has told you. Check with them if you are unsure.

How do I take Truqap?

Truqap is available in two forms.

CAV 200

Truqap 200 mg

is a beige capsule-shaped tablet. It reads 'CAV 200' on one side and the other side is plain.

CAV 160

Truqap 160 mg

is a beige, round tablet. It reads 'CAV 160' on one side and the other side is plain.

You will usually start with the 200 mg tablets.

Truqap is usually taken as two tablets (200 mg), twice a day for 4 days in a row. This is followed by a 3-day break. This means for 4 days:

- You will take two tablets of Truqap in the morning (i.e. 7 am)
- You will take another two tablets of Truqap in the evening, about 12 hours later (i.e. 7 pm)

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
 AM 	 AM 	 AM 	 AM 	No Dose	No Dose	No Dose
 PM 	 PM 	 PM 	 PM 			

Then, for the next 3 days you will not take any tablets.

You should repeat this process every week.

The 4 days of the week that you take Truqap will depend on the day you started taking it. For example, if the first day you took Truqap was a Wednesday, you would take Truqap from Wednesday to Saturday and then not take it from Sunday to Tuesday.

You may find it helpful to record the first day that you start taking Truqap on the packaging of your medication. A dedicated space for this information can be found on the side of the box.

 **Truqap™**
capiivasertib
160 mg • 200 mg tablets

Record starting day of the week (Day 1) here:

DO NOT CHANGE YOUR DOSE OR STOP TAKING YOUR TREATMENT UNLESS YOUR CANCER CARE TEAM TELLS YOU TO.

Depending on how your body responds to treatment with Truqap, your doctor may want to adjust your Truqap dose. **It is very important to follow your cancer care team's advice.**

The number of tablets taken depends on the dose prescribed.

For example, you might be asked to take:

Two 200 mg tablets taken twice per day

or

Two 160 mg tablets taken twice per day

or

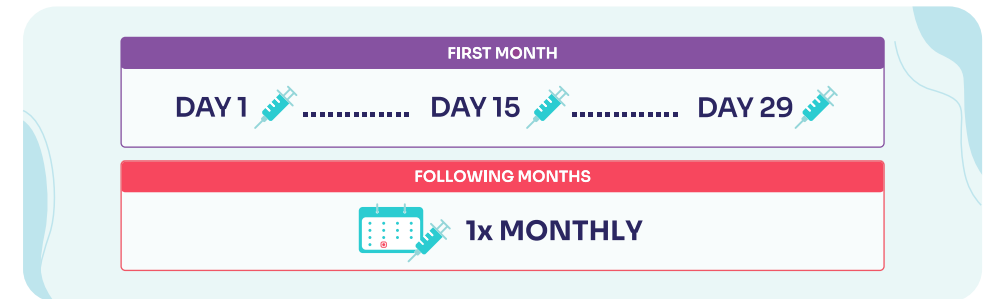
One 200 mg tablet taken twice per day

Having open, honest conversations with your cancer care team can help with managing your side effects more effectively.

If you have any concerns about how to take Truqap, don't hesitate to ask your cancer care team for advice.

HOW WILL I BE GIVEN FULVESTRANT?

Fulvestrant is a hormone therapy that your doctor will give to you by injection in the buttocks. During your first month of treatment, you will be given injections on **days 1, 15 and 29**. After that, you will receive these injections once a month.



You should read the fulvestrant Patient Information Leaflet (PIL) for important warnings and precautions and other information related to fulvestrant. If you have any concerns about your fulvestrant treatment, don't hesitate to ask your cancer care team.

KEEPING TRACK OF YOUR DOSING SCHEDULE

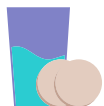
Record your own dosing schedule on your dosing card. This card can be kept in your wallet or purse and is designed to help you keep track of when you should take your treatment.

If you haven't got a dosing card already but would like one, please ask your cancer care team who should be able to provide you with one.

The image shows a 'My Truqap and fulvestrant treatment card'. It includes the Truqap logo and the text 'capiasertib 160 mg • 200 mg tablets'. The card is divided into two main sections. The left section is for Truqap treatment, asking 'For my Truqap treatment, I take:' and providing checkboxes for 'Two 200 mg tablets', 'Two 160 mg tablets', and 'One 200 mg tablet'. It also asks 'At: (these times should be 12 hours apart)' with fields for 'am' and 'pm', and 'On: (please circle 4 consecutive days)' with a row of days 'M T W T F S S'. The right section is for fulvestrant treatment, asking 'In my first month of fulvestrant treatment, I will have: (please insert dates)' and providing fields for 'Injection 1:', 'Injection 2 (15 days later):', and 'Injection 3 (29 days later):'. A vertical banner on the right edge of the card reads 'DO NOT STOP OR CHANGE YOUR TREATMENT UNLESS TOLD TO BY YOUR CANCER CARE TEAM'.

TAKING YOUR MEDICATION

When taking Truqap, remember to:



Drink water

Take Truqap with a glass of water. The tablets can be taken with or without food.



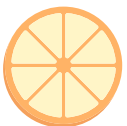
Stick to your schedule

Don't double your dose, even if you vomit after taking Truqap. Take your next dose at your usual time.



Swallow the tablet whole

Do not chew, crush or split your tablets, or take any tablets that are broken, cracked or damaged. If you have difficulty swallowing tablets, talk to your cancer care team – they may be able to help.



Avoid eating grapefruit

Avoid eating grapefruit. High doses of grapefruit and grapefruit juice while you are taking Truqap may increase the side effects of Truqap.



Tell your doctor about any other medicines you take

Tell your doctor about all the medicines you take, including those you may buy from the pharmacy or supermarket, including herbal medicines. This is because Truqap may affect the way other medicines work, and other medicines may affect how Truqap works.



Take special care when driving

Truqap may affect your ability to drive or use machines. If you feel tired while taking Truqap, take special care when driving or using tools or machines.

What if I forget to take Truqap?

If it is less than 4 hours since when you should have taken Truqap, you can still take your dose.

If it has been more than 4 hours, skip this dose. Take your next dose at your usual time.

For example, if you normally take Truqap at 7 am, you can take it up until 11 am. If it is after 11 am, you should wait until 7 pm and take your next dose as normal.

What if I take more Truqap than I should?

If you take more Truqap than you should, contact your doctor or a hospital straight away. If possible, show them the Truqap packet.

REMEMBERING TO TAKE TRUQAP AT THE RIGHT TIME:

In addition to recording which day of the week you start your treatment on the medication packet and using your dosing card, you may find some of the following suggestions helpful:

- It might be helpful to put a small whiteboard up in your kitchen and write down your dosing schedule. Tick off each dose once you have taken it
- Set up reminders on your phone to go off at the same time twice a day
- Ask your partner or a family member to remind you to take your medication, so they are able to help if you forget
- Get a pill organiser. These are plastic boxes with compartments for your medicines, to remind you when they need to be taken. Ask your cancer care team if they can provide you with one
- Establish a routine and link your medication to a habit you already have (for example if you brush your teeth at 7 am and 7 pm, take Truqap before doing this)

WARNINGS AND PRECAUTIONS

Before you take Truqap, tell your healthcare provider if:

- You have or have ever had high blood sugar or diabetes (or signs of high blood sugar, such as being very thirsty and having dry mouth, needing to pass urine more often than usual, making greater amounts of urine than usual, increased appetite with weight loss)
- You have any current infections
- You have diarrhoea or loose stool
- You have rash or other skin disorders
- You have kidney problems or high levels of creatinine or uric acid in your blood
- You have liver problems
- You are taking or have recently taken any other medicine, including medicines obtained without a prescription
- You are pregnant or plan to become pregnant. Truqap may harm your unborn baby. If you are able to become pregnant, you should use an effective method of birth control during your treatment and at least for 4 weeks after the last dose of Truqap
- You are breastfeeding or plan to breastfeed. It is not known if Truqap passes into your breast milk. Do not breastfeed during treatment
- You are a male with female partners who are or are able to become pregnant. Male patients should use condoms and effective birth control during treatment with Truqap and for 16 weeks after the last dose. If your female partner becomes pregnant, tell your cancer care team right away
- You have poor dental health or history of osteonecrosis of the jaw

Immediately talk to your doctor if you experience the following during treatment with Truqap:

High blood sugar levels (hyperglycaemia)

- Your doctor, pharmacist or nurse will monitor your blood sugar levels before you start and at regular intervals during treatment with Truqap. This will be more often in the first 8 weeks of treatment. Your blood sugar levels should be monitored on days 3 or 4 of the dosing week, before you take your Truqap dose
- Your doctor, pharmacist or nurse will tell you exactly when and where to have the blood tests. Treatment with Truqap may only be started if tests show that you have the right levels of sugar in your blood. This is because Truqap can increase the amount of sugar in your blood (this is known as hyperglycaemia), which can become serious and cause complications (such as diabetic ketoacidosis – please see page 19 for more details)
- If you have diabetes or other risk factors associated with high blood sugar, your cancer care team may advise more frequent monitoring
- For signs of high blood sugar – see page 18, 'Before taking Truqap', to learn more about understanding and managing side effects. Additional symptoms such as nausea, vomiting, abdominal pain, difficulty breathing, fruity odour on breath, confusion, unusual fatigue or sleepiness may be signs of an acute complication of increased blood sugar. **If you have any of these symptoms, immediately talk to your doctor, call 999 or visit A&E for urgent medical attention. If you call 999 or visit A&E, inform the emergency team that you are taking Truqap and fulvestrant**

Any signs of diarrhoea

- Your doctor, pharmacist or nurse will advise you to drink more fluids or take medicines to treat diarrhoea

Any skin reactions

- For signs of skin reactions – see page 19 to learn more about understanding and managing side effects

Problems with your mouth, teeth or jaw

- New or worsening oral symptoms including dental health, pain or swelling and non-healing of mouth sores or discharge

Your doctor may need to treat these symptoms, temporarily pause your treatment, reduce your dose or permanently stop your treatment with Truqap.

WHEN WILL I NEED MY BLOOD SUGAR LEVELS CHECKED?

Your blood sugar levels will be monitored before and during your treatment with Truqap. This is because it can cause high blood sugar, known as hyperglycaemia.

How often these are tested throughout your treatment can depend on factors such as whether you have diabetes or other risk factors for high blood sugar, and what your cancer care team decides is best for you and your needs. You can find more information about how often you may need to be tested in the following sections.

Your blood sugar will be tested in two different ways:

- **Fasting glucose:** A blood test that measures your blood sugar when you have not eaten or drunk anything (except water) for at least 8 hours
- **HbA1c:** A blood test that shows your average blood sugar over the past 3 months

FOR PEOPLE WITHOUT DIABETES

Once you have started Truqap, your blood sugar levels could be checked at weeks 1, 2, 4, 6 and 8. After that, they may be checked monthly. The test should be done on day 3 or 4 of your dosing week before your dose is taken that day.

Example of blood sugar testing schedule

Day	1	2	3	4	5	6	7
Fasting glucose test							
Truqap dose					No dose		

 Your HbA1c will be checked once every 3 months after starting Truqap. This will help your cancer care team see how your blood sugar levels are averaging over a longer period.

FOR PEOPLE WITH DIABETES

Once you have started taking Truqap, your blood sugar levels may be checked at weeks 1, 2, 4, 6 and 8. You could be asked to monitor these daily for the first 2 weeks of treatment. This should be done before you take your dose each day.

After 2 weeks, your cancer care team will let you know how often you need to check your blood sugar. This can depend on how stable your blood sugar is.

Example of week 1 and 2 blood sugar testing schedule

Day	1	2	3	4	5	6	7
Fasting glucose test							
Truqap dose					No dose		

 You may require an HbA1c test at week 4 after starting Truqap. After this, HbA1c will be monitored once every 3 months to get an average of your blood sugar levels over a longer period.

FOR PEOPLE WITH AND WITHOUT DIABETES

Depending on how high your blood sugar gets, your doctor may pause your Truqap treatment, lower the dose or stop it completely.

Your monitoring plan may be different from the tables shown. It is important to follow the instructions given by your cancer care team.

TRACKING MY BLOOD SUGAR LEVELS

If you are asked to check your blood sugar at home, your cancer care team will show you how to do this and what numbers to look out for.

You can use the table below to record your blood sugar readings and keep track of them. **Be sure to test your blood sugar levels before taking your Trugap dose.**

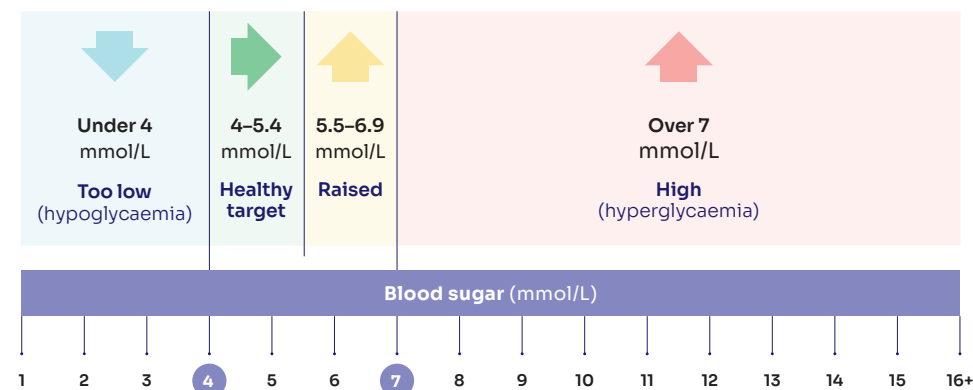
It is important that you do not eat or drink anything (except water) for at least 8 hours before checking your blood sugar. You may find it helpful to fast overnight and test first thing in the morning before breakfast.

If you run out of space or prefer another format, you can record your readings in another way, such as using a phone app or notebook.

[illegible]

WHAT DO MY READINGS MEAN?

The visual below is designed to help you understand what different blood sugar readings can mean. These targets apply to people without diabetes and are based on fasting glucose levels (measured before eating or drinking).*



Immediately talk to your doctor if you experience high blood sugar levels during treatment with Trugap.

Diabetic ketoacidosis (DKA) can be a serious complication of hyperglycaemia. Immediately contact your doctor, call 999 or visit A&E if you have any of the symptoms of DKA. Visit page 19 of this booklet to read more about these.

***People with diabetes often have blood sugar level targets that may be different from the general guidance shown above. It is important to follow your cancer care team's advice about your own target levels.**



Remember that your cancer care team is there to guide you throughout your treatment journey. They can answer any questions you have about your treatment.



BEFORE TAKING TRUQAP

Like all medicines, Truqap can cause side effects, although not everybody gets them.

SOME SIDE EFFECTS CAN BE SERIOUS

Immediately talk to your cancer care team if you experience the following during treatment with Truqap. Your cancer care team may need to treat these symptoms, temporarily pause your treatment, reduce your dose or permanently stop your treatment with Truqap.

High blood sugar levels (hyperglycaemia, very common, may affect more than 1 in 10 people)

Signs to look out for:

- Excessive thirst and dry mouth
- Increased appetite with weight loss
- Needing to pass urine more often than usual or producing greater amounts of urine than usual

Management:

Your doctor will:

- Advise on lifestyle changes if you have an increased risk of or develop high blood sugar during treatment

Based on your blood sugar test results, your doctor may:

- Prescribe (or intensify prior) antidiabetic treatment if your blood sugar levels are high
- Change your treatment dose. Based on the severity of hyperglycaemia, your dose may be lowered, paused or stopped

Risk factors for hyperglycaemia

There are several factors that can increase the risk of hyperglycaemia such as:

- **Other health conditions** such as diabetes that isn't well controlled, infections, kidney problems or diarrhoea can raise your blood sugar
- **Certain medicines** can raise your blood sugar or make it harder for your body to use insulin properly
- **Lifestyle factors** such as not drinking enough water, drinking too much alcohol, being overweight or not getting enough nutrients from your food can raise your blood sugar. For tips on how to manage high blood sugar levels with your diet, scan or click the QR code for the Diabetes UK website

This website is not owned or managed by AstraZeneca.



Diabetic ketoacidosis (uncommon, may affect up to 1 in 100 people)

Diabetic ketoacidosis (DKA) is a serious complication that can happen in people due to hyperglycaemia. It's where a lack of insulin causes harmful substances called ketones to build up in the blood. It can be life threatening and needs urgent treatment in hospital.

Contact your cancer care team/doctor immediately or call 999 or go to A&E if you notice any of the following symptoms:

- Nausea
- Vomiting
- Abdominal pain
- Difficulty breathing
- Fruity odour on breath
- Feeling unusually tired or sleepy
- Feeling confused

Skin reactions (very common, may affect more than 1 in 10 people)

Signs to look out for:

- Rash
- Reddening of the skin
- Blistering of the lips, eyes or mouth
- Skin peeling
- Skin inflammation with rash
- Shedding and/or scaling of skin surface
- Skin eruptions
- Toxic skin eruptions (allergic rash)
- Feeling unusually tired or sleepy

Management tips:

- Avoid body washes or lotions that contain dyes or perfumes
- Switch to dye- and fragrance-free washing detergents

OTHER POTENTIAL SIDE EFFECTS OF TRUQAP

Below are some other side effects you may experience with Truqap. Tell your cancer care team if you notice any of the following:

Very common (may affect more than 1 in 10 people)

- Urinary tract infection
- Low level of red blood cells (anaemia)
- Loss of appetite
- Nausea
- Vomiting
- Diarrhoea
- Mouth sores or ulcers with gum inflammation
- Itching
- Tiredness, or feelings of weakness

Common (may affect up to 1 in 10 people)

- Hypersensitivity
- Reduced level of potassium in the blood (hypokalaemia)
- Strange taste in the mouth
- Upset stomach, indigestion
- Dry skin
- Fever
- Pain, redness and swelling of mucosa in different parts of the body, e.g. genital mucosa
- High blood levels of creatinine
- Weight loss
- High blood levels of glycosylated haemoglobin (a marker of blood sugar level over the last 8 to 12 weeks)

We understand that experiencing side effects while undergoing cancer treatment may be challenging but remember that your cancer care team is there to support you. Together, you may be able to find ways to make side effects more manageable.

Consult your Patient Information Leaflet (PIL) for full information.

KEEPING TRACK OF SYMPTOMS AND ANY POTENTIAL SIDE EFFECTS

It may be difficult to remember how your symptoms or any potential side effects you may experience change over your treatment course, especially when you have other things on your mind.

If you find it helpful, you can use this space to make notes about how you're feeling about your treatment, as well as any symptoms or side effects you're experiencing. This may be helpful for starting or guiding your conversations with your cancer care team, especially if you feel anxious during those appointments.

Remember to write down:

- The date and time when you make your note so that you can track how your symptoms change
- Details of any side effects you experience – make a note of how severe the symptom was and how it affected you
- Any doses you miss of your treatment and why

You don't need to use this space if it doesn't work for you – you could choose to record the information in an app on your phone or use a small notebook instead. Whichever approach you choose, try to bring it to every appointment you have with your cancer care team.

Immediately contact your cancer care team or doctor if you experience any side effects as well as making a record of them.

Remember that every person's experience of breast cancer treatment is unique and there is no right or wrong way to feel.

Please refer to your Patient Information Leaflet (PIL) for more information.

Reporting side effects

▼ This medicine is subject to additional monitoring.

This will allow quick identification of new safety information.

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/> or via the 'MHRA Yellow Card' app in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

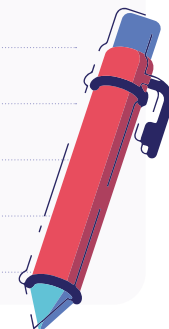
Side effects can also be reported to AstraZeneca in the following ways:

Online: <https://contactazmedical.astrazeneca.com>

Email: Medical.InformationUK@astrazeneca.com | Telephone: 0800 783 0033

Date/Time

Notes



ADDITIONAL LEARNING AND SUPPORT

At your appointments, your cancer care team will ask you questions about how you've been feeling and how you have been finding your treatment. It may be useful to think about how you may respond before your appointments so you can make the most of them.

Be open and honest, so your cancer care team can work out how best to help you.

PLANNING FOR YOUR APPOINTMENT

Remember your appointment is about you and it's also your opportunity to ask questions.

It's important to share if you are unsure or confused by anything or if you are struggling with anything in your day-to-day life, including your mental health. Cancer can affect many parts of your life; your cancer care team are there to help with this. Here are some questions you might want to ask:

- **How is this treatment different to others I have had before?**
- **How often will I need to see a healthcare professional during this treatment?**
- **How often will my treatment be reviewed?**
- **How will I know if the treatment is working?**
- **What treatment goals can I set?**
- **Can I work as normal?**
- **Will Truqap impact my mood?**
- **Can I still drink alcohol while undergoing my Truqap treatment?**
- **Can I go on holiday while having my Truqap treatment?**
- **Will this treatment impact my sex life?**
- **Will I still be able to exercise while taking Truqap?**

DEFINITIONS OF COMMONLY USED TERMS

You may have heard a lot of unfamiliar terms or words since your diagnosis. If there's anything you don't understand, remember that your cancer care team are on hand to help you understand.

We've included some commonly used terms below, which you can refer back to.

Biomarker	A molecule found in your body's tissues, blood or other bodily fluids that can be used to see how well the body responds to a treatment for a disease. In people with breast cancer, biomarker testing is done to find out the hormone receptor status of the tumour (e.g. HR+).
Gene alterations	Changes to your genes such as <i>PIK3CA</i> , <i>AKT1</i> and/or <i>PTEN</i> . You may also hear people describe this as a 'gene mutation'.
HER2-	Human epidermal growth factor receptor 2 (HER2) is a gene that provides instructions in the body to make HER2 receptors. These receptors can be found on the surface of breast cancer cells. In some people with breast cancer, there can be too many HER2 proteins being made. This is known as HER2-positive breast cancer (HER2+). In others, there can be normal levels of HER2 proteins in the body. This is known as HER2-negative breast cancer (HER2-).
HR+	HR+ stands for hormone receptor positive. This means that your breast cancer is the type that is sensitive to hormones like oestrogen or progesterone, which can encourage breast cancer cells to grow.
Hormone therapy	A treatment that stops or slows down the growth of breast cancers that use hormones in your body to grow.
Metastatic disease	The spread of cancer from where it started to other places in the body.
Protein	These are essential 'building blocks' in the body. Proteins are important in all types of bodily functions, from digestion and metabolism to growth and repair.
Stable disease	When a cancer is neither growing nor shrinking.



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