

A Patient's Guide to Cabometyx® (cabozantinib)





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About this booklet

About this booklet

This booklet has been developed to provide practical information on advanced kidney cancer and taking Cabometyx® and includes the following topics:

- What is Cabometyx®?
- · What to expect from your treatment
- Possible side effects
- Managing side effects

It is important to inform your doctor and medical team of any concerns about any side effects you experience when taking Cabometyx®. To help you, this booklet contains a treatment diary section where you can record your side effects, keep track of your appointments and write down any questions for your doctor or nurse.

For more information, please read the Patient Information Leaflet (PIL) that comes in the package containing your medication.

How does Cabometyx® work?

Cabometyx® belongs to a group of therapies called tyrosine kinase inhibitors; it blocks several pathways involved in the growth and spread of cancer cells.

All cells have signals that tell them when to grow, when to divide and even when to die. However, unlike normal cells, cancer cells don't stop growing and dividing when they should.

This out-of-control growth is what can cause tumours to form.

Cabometyx® works by binding to certain protein receptors on the cancer cells in the body and blocking some of the 'grow and divide' signals. This can stop the growth of blood vessels that feed cancer cells, helping cut off their blood supply and slowing the rate at which the cancer cells grow.



Figure adapted from Cabometyx® Patient Information Leaflet.

How should you take Cabometyx®?



Tablet shown not actual size

✓ The usual dose of Cabometyx® is 60 mg; however, there are two other doses available, and your doctor will decide which is right for you.



✓ Take your Cabometyx® tablet once a day, at the same time every day. You should not eat for at least 2 hours before or 1 hour after taking it.



✓ Swallow the tablet whole with a glass of water.

Do not crush the tablet or take it with food.



What safety precautions should you follow when taking Cabometyx®?



Do not drink grapefruit juice, eat grapefruit or take supplements that contain grapefruit during treatment with Cabometyx[®].



If you are intolerant to some sugars, including lactose, talk to your doctor before taking Cabometyx[®].



➤ Do not take Cabometyx® if you're pregnant, breastfeeding or planning to become pregnant. There is a possibility your fertility could be affected by this treatment. If you or your partner could become pregnant, use contraception during your treatment and for at least 4 months after your treatment has finished. Talk to your doctor about which methods of contraception are appropriate while you're taking Cabometyx®.



Some medicines can interact with each other, affecting the way they work. It is important that you tell your doctor about any other medicine you may be taking, even if you don't take it every day or if you have bought it yourself. You may want to keep a record of these in the diary section at the back of this booklet. For a full list of medicines you should discuss with your doctor if you are taking them, please check the PIL.

What if you forget to take your Cabometyx®?



Figure adapted from Cabometyx® Patient Information Leaflet.



Do not take a double dose (two doses at the same time) to make up for a missed dose. If you take more than your normal dose, let your healthcare team know straight away.



Do not take tablets after the expiry date noted on the bottle label and carton (after 'EXP'), which refers to the last day of that month.

Side effects

Side effects

What are the side effects of Cabometyx®?

This section of the booklet is here to provide information on side effects you may experience when taking Cabometyx® and tips to help you manage them.

The start of your treatment is a crucial time for monitoring; during this time, your doctor or nurse will be able to tell how you're reacting to the treatment and if you're experiencing any side effects.

Like all medicines, Cabometyx® may cause some side effects. However, each person will respond differently and not everybody will experience side effects. If you experience any side effects, your healthcare team may lower your dose or interrupt your treatment temporarily. They may prescribe other medicines to help manage them.

There are also ways to help you manage any side effects at home, including eating healthily and getting enough rest. To find out more, visit **https://surviveandthrive.ie** to access resources and information recommended to help manage side effects or discomfort during treatment.

For more information, and for a full list of possible side effects, please refer to your Cabometyx® PIL and ask your doctor, nurse or pharmacist if you have any questions.

Side effects

What are the very common side effects of Cabometyx®?

Very common side effects of Cabometyx® include:

- Anaemia
- Tiredness, weight gain, constipation, feeling cold and having dry skin, which can be symptoms of reduced thyroid function
- Changes in blood and liver function tests
- Decreased appetite and an altered sense of taste
- Headache and dizziness
- High blood pressure (hypertension)
- Bleeding
- Difficulty speaking, hoarseness, a cough and shortness of breath

- Stomach upset, including diarrhoea, nausea, vomiting, constipation, indigestion and abdominal pain
- Redness, swelling or pain in the mouth or throat (stomatitis)
- Skin rash (sometimes with blisters), itching and pain in the hands or soles of the feet
- Pain in the arms, hands, legs or feet
- Feeling tired or weak
- Swelling of the legs and arms
- Weight loss

Very common side effects may affect more than 1 in 10 people. Common side effects may affect up to 1 in 10 people. Uncommon side effects may affect 1 in 100 people. For a full list of side effects, please refer to your Cabometyx® PIL and ask your doctor, nurse or pharmacist if you have any questions.

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects that are not listed in this booklet or in the PIL.

Hypertension (high blood pressure)



Hypertension is very common with Cabometyx® and often has no symptoms but can be severe. Symptoms include headaches, nosebleeds and/or difficulty breathing.

Your doctor or nurse will check your blood pressure regularly throughout your treatment. If needed, you may be prescribed additional medication to treat any hypertension. You may also find it helpful to use a blood pressure monitor at home; talk to your doctor about what a normal blood pressure range would be for you.

Call your doctor or nurse straight away if you:



Have headaches



Have nosebleeds



Feel dizzy

Tips to help manage hypertension:

- Have your blood pressure checked regularly
- Eat a balanced diet of whole grains, fruits, vegetables and low-fat dairy products (such as yogurt)
- Limit your intake of salt, caffeine and alcohol
- Exercise regularly and ask your doctor what types of exercise they would recommend for you
- Talk to your doctor before using any prescription or non-prescription medicines to help with your symptoms

Diarrhoea



Diarrhoea is when you frequently pass loose or watery stools; you may be prescribed additional medication to treat this.

Call your doctor or nurse straight away if you:



Have six or more loose bowel movements a day for more than 2 days in a row



Have blood around the anal area or blood in your stools



Lose weight due to diarrhoea



Have pain or cramps in your belly that last for more than a day



Have a fever of 38°C or higher

Tips to help manage diarrhoea:

- Drink plenty of clear liquids (water, apple juice, clear broth)
- Try not to drink many caffeinated drinks (such as coffee and soft drinks) or dairy products (such as milk) and avoid alcohol
- Eat small, frequent meals, including foods such as bananas, rice, stewed apple, dry toast or mashed potatoes
- Try not to eat foods that are spicy, greasy, fatty or high in fibre (fast food, raw vegetables, nuts) and avoid dairy
- Keep track of how often you have diarrhoea, the amount of fluid you drink and your weight
- After each bowel movement, gently clean your anal area well with a mild soap or baby wipe and pat dry. Once dry, you may apply petroleum jelly or a nappy rash ointment to the outer rectal area

Fatigue (feeling tired or weak)



Cabometyx® may make you feel more tired than usual, and you may experience headaches or dizziness. Cabometyx® may affect your ability to drive or use machines. You may find that you feel too tired to get out of bed or after doing small activities or have trouble thinking clearly or getting to sleep at night.

Tips to help manage fatigue:

- ✓ Try to get a good night's sleep each night; the right amount varies by person but is usually around 7–8 hours
- Maintain good sleep habits; go to bed at the same time each night and wake up at the same time each morning
- ✓ If you have anything containing caffeine, make sure it is 6–8 hours before you go to bed
 - Remember, caffeine can be present in liquids, such as soft drinks and coffee, and food, including chocolate
- Make sure your bedroom is dark, quiet and a comfortable temperature
- Be as active as possible; talk to your doctor about which types of activity may be right for you
- Plan ahead; decide which activities are most important to you and try to schedule important activities throughout the day, if possible, so you can take breaks
- Eat a nutritious and well-balanced diet
- Consider meeting with a dietitian

Mouth, throat and breathing problems



You may experience mouth, throat and/or breathing problems when taking Cabometyx®. These can include redness, pain or swelling in the mouth or throat, difficulty speaking, hoarseness, a cough or changes in taste. You may also get mouth ulcers.



Call your doctor or nurse straight away if you have pain in your mouth or throat.

Tips to help manage mouth and oral care:

- Check your mouth daily for any changes
- See your dentist before you start treatment
- Brush your teeth gently after each meal
- Use a soft toothbrush and children's toothpaste
- Floss your teeth
- If you have dentures that have become ill-fitting, they should be replaced or removed
- Do not use mouthwash containing alcohol; use a salt and baking soda mixture
 - Add 1 teaspoon of salt and 1 teaspoon of baking soda to 1 pint of warm water, stir or shake well. Sip the solution, swish it around in your mouth, gargle gently and spit it out. Don't swallow!
- Use a lip balm to keep your lips moisturised

Mouth, throat and breathing problems



Tips to help with mouth pain:

- ✓ Suck on ice chips or ice pops
- Drink through a straw
- ✓ Talk to your doctor about over-the-counter medication that can be used for the pain
- ✓ Eat soft foods that you can swallow easily
- Try not to eat hard, crusty, salty, sticky, sugary or spicy foods
- Try not to eat or drink fruits or juices that are acidic, such as tomatoes, oranges, limes and lemons

Stomach upset



You may experience stomach issues, including nausea, diarrhoea (see page 12), vomiting, constipation, indigestion and abdominal pain.

Call your doctor or nurse straight away if you:



Vomit 1–2 times in 24 hours



See blood in your vomit



Vomit and it looks like coffee grounds



Can't have more than four cups of liquid or ice chips in a



Haven't been able to eat for more than 2 days



Feel weak, dizzy or confused



Have dark yellow urine

Tips to help manage nausea and vomiting:

- Drink clear, sweet liquids, like fizzy drinks or fruit juice (except orange or grapefruit juice, which may irritate your stomach)
- Eat bland foods (with little to no taste), such as dry toast, crackers and ginger biscuits. Do not eat heavy, fatty meals or greasy foods
- Suck lemon or mint sweets

Your doctor may prescribe medication to help manage any nausea and vomiting.

Hand-foot skin reactions



Hand-foot skin reactions can cause soreness in the palms of your hands and soles of your feet and can be severe.

Tell your doctor or nurse straight away if you have rashes, redness, pain or blisters on your hands or feet. You may be given moisturising creams or ice packs to help manage any reactions.

Call your doctor or nurse if you have any of the following problems with your hands or feet:



/!\ Redness or swelling



Tingling/burning or sensitivity to touch



Blisters



Cracked, flaking or peeling skin

Tips to help with hand-foot skin reaction:

- Avoid heat, hot water and direct sunlight
- Use ice packs to cool your hands and feet
- Take cool showers or baths
- Try to avoid pressure, friction or rubbing against your hands and feet
- Wear comfortable. well-fitting footwear
- Gently pat your skin dry after washing your hands or bathing
- Wear cotton gloves and socks to help protect your hands and feet
- Use a mild, fragrance-free lotion or moisturising cream. Talk to your doctor or pharmacist about which creams may be appropriate for you

Serious side effects

Signs that you may need urgent medical treatment

You may experience some side effects you cannot manage at home and require immediate medical attention. You should contact your doctor immediately or go to the Emergency Department at your nearest hospital if you experience any of the following:

Severe or uncontrollable bleeding (haemorrhage)

Symptoms include:



/!\ Coughing up blood



Vomiting blood



Black stools



🚹 Any unusual or heavy bleeding



/!\ Blood in urine

Severe gastrointestinal symptoms

Symptoms include:



Tenderness or pain in the stomach area



Pain in the abdomen



Severe nausea (feeling sick) or vomiting (see page 16)



Severe constipation



Fever

Serious side effects

Signs that you may need urgent medical treatment

You may experience some side effects you cannot manage at home and require immediate medical attention. You should contact your doctor immediately or go to the Emergency Department at your nearest hospital if you experience any of the following:

Posterior reversible encephalopathy syndrome

Symptoms include:



/!\ Headaches



Fits



Confusion



Difficulty concentrating



Swelling or shortness of breath



A wound that does not heal

Pain in the mouth, teeth and/or jaw

Symptoms include:



Swelling or sores inside the mouth



Numbness or a feeling of heaviness in the jaw



Loosening of a tooth



Feeling drowsy, confused or losing consciousness

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects that are not listed in this booklet or in the PIL.

Your treatment journey

Your treatment journey

Signs that you may need urgent medical treatment

At the start of your treatment, your doctor or nurse will be closely monitoring you to see how you're reacting to your treatment and determine if your dose needs to be adjusted.

At each appointment, your healthcare team will carry out various health checks, such as performing blood tests or taking your blood pressure.

It is important to talk to your healthcare team regularly about your treatment, how you're feeling and any side effects you may have experienced and to ask any questions you may have. To support you with this, this booklet includes a treatment diary, a side effects tracker and an appointment tracker.

The treatment diary is for you to record any questions you may have, how you're feeling after treatment and any details of your treatment you may want to discuss with your doctor or nurse.

The side effects tracker will help you keep a record of any side effects you may experience to discuss with your doctor or nurse.

The appointment tracker is to help you manage your appointment schedule.

Remember to bring this booklet to all your appointments so that you can discuss any issues with your doctor or nurse.

WEEK 1	Date:
Notes:	
Things to discuss at next ap	ppointment:

WEEK 1	Date:	
Notes:		
Things to discuss a	t next appointment:	

WEEK 2	Date:	
Notes:		
Things to discuss a	t next appointment:	

WEEK 3	Date:	
Notes:		
Things to discuss at	t next appointment:	

WEEK 4	iiii Date:	
Notes:		
Things to discuss at	t next appointment:	

WEEK 5	Date:	
Notes:		
Things to discuss a	at next appointment:	

WEEK 6	Date:	
Notes:		
Things to discuss a	at next appointment:	

WEEK 7	Date:	
Notes:		
Things to discuss a	at next appointment:	

WEEK 8	Date:	
Notes:		
Things to discuss a	nt next appointment:	

Appointment tracker

Appointment tracker

It is very important to attend every appointment you have with your doctor or nurse.

To help you remember, you can record their details below and keep this booklet close by. You may want to bring a family or friend to these appointments for support.



APPOINTMEN	T 1	
Date	© Time	O Location
Notes from our sint		
Notes from appoint	ment:	
APPOINTMEN	⊤ 2	
Date	L Time	O Location
Notes from appoint	ment:	

APPOINTMEN	⊤3	
Date	□ Time	O Location
Notes from appoint	ment:	
APPOINTMEN	⊤4	
Date	© Time	© Location
Notes from appoint	ment:	

APPOINTMEN	⊺5	
Date	□ Time	⊚ Location
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APPOINTMEN	⊤6	
iiii Date	© Time	◎ Location
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⊤8	
① Time	◎ Location
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This tracker has been created to help you keep track of any side effects you may experience over the next 8 weeks. Here you can keep a record of any side effects you experience and when you experienced them.

This is important because it will help your doctor or nurse see how you're responding to your treatment and determine whether you need to have your dose changed or treatment stopped.

You can also make additional notes on how often you experience side effects, the severity of your side effects and how you've tried to manage them at home or write down any questions you may want to ask.

Remember, some side effects may require you to call your doctor or nurse immediately or seek urgent medical treatment (see pages 18–19).

Example of how to fill in your side effects tracker:		
WEEK 1		
Monday	9	Side effects: Yes X No
Side effect notes: Vomited twice in the afternoon Took two lozenges in the evening		
Blood pressure:* 90/60 mmHg	Glasses of water/liquid: 8 glasses of water	Weight: 65 kg

Monday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Tuesday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Wednesday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Thursday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:

^{*}If monitoring at home.

	Side effects: Yes No
Glasses of water/liquid:	Weight:
	Side effects: Yes No
Glasses of water/liquid:	Weight:
	Side effects: Yes No
Glasses of water/liquid:	Weight:
	Glasses of water/liquid:

^{*}If monitoring at home.

Monday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
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Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
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Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Thursday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:

^{*}If monitoring at home.

Friday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Saturday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Sunday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:

^{*}If monitoring at home.

Monday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Tuesday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Wednesday		Cide offeren Ves Ne
wednesday		Side effects: Yes No
Side effect notes:		Side effects: Yes No
		Side effects: Yes No
	Glasses of water/liquid:	Weight:
Side effect notes:	Glasses of water/liquid:	
Side effect notes:	Glasses of water/liquid:	
Side effect notes: Blood pressure:*	Glasses of water/liquid:	Weight:
Side effect notes: Blood pressure:* Thursday	Glasses of water/liquid:	Weight:
Side effect notes: Blood pressure:* Thursday	Glasses of water/liquid:	Weight:
Side effect notes: Blood pressure:* Thursday Side effect notes:		Weight: Side effects: Yes No

^{*}If monitoring at home.

Friday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Saturday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
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Side effect notes:		
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Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Wednesday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Thursday		Side effects: Yes No
Side effect notes:		
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Blood pressure:*	Glasses of water/liquid:	Weight:
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^{*}If monitoring at home.

Friday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
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Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
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Side effect notes:		
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Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Wednesday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
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Side effect notes:		
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Blood pressure:*	Glasses of water/liquid:	Weight:
Saturday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:
Sunday		Side effects: Yes No
Side effect notes:		
Blood pressure:*	Glasses of water/liquid:	Weight:

^{*}If monitoring at home.

If you respond to your Cabometyx® treatment within about 8 weeks and any side effects are being managed, your appointments with your doctor or nurse will become less frequent. However, they will still be there to provide support when needed.

Remember, you are not alone. In addition to speaking with your doctor or nurse, you may want to seek support from your family and friends during this time.

There is also a range of support and information services you can access to provide further support during your treatment journey.



The list below is a small selection of patient resources and support groups that you can find locally or online:

Ireland:

Irish Cancer Society
www.cancer.ie
01 231 0500 / 01 800 200 700

Marie Keating Foundation www.mariekeating.ie
01 628 3276

ARC Cancer Support Centres

www.arccancersupport.ie65 Eccles Street, Dublin 701 830 7333

Or

557/559 South Circular Road, Dublin 8 **01 707 8880**

The list below is a small selection of patient resources and support groups that you can find locally or online:

UK & abroad:

Macmillan Cancer Support

www.macmillan.org.uk

Macmillan Support Line can help with clinical and practical information.

0044 808 808 00 00

(7 days a week, 8 am-8 pm)

A PDF booklet on understanding kidney cancer can be downloaded from:

www.macmillan.org.uk/cancer-information-and-support/stories-and-media/booklets/understanding-kidney-cancer

You can also talk to other patients in Macmillan's Online Community:

www.macmillan.org.uk/community

Kidney Cancer UK

www.kcuk.org.uk

0044 122 387 0008

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Notes

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Please read the PIL that comes in the package with your medication and speak to your doctor, nurse or pharmacist.

Reporting of side effects:

If you experience 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 to the HPRA. Reporting forms and information can be found at

www.hpra.ie or email medsafety@hpra.ie.

Adverse events should also be reported to the Ipsen Medical Information Department on +353 (0)1 809 8256 or pharmacovigilance.uk-ie@ipsen.com.

By reporting side effects you can help to provide more information on the safety of this medicine.