

Your KEYTRUDA[®] (pembrolizumab) and KISPLYX[®] (lenvatinib) Treatment Guide and Diary



This patient information booklet has been developed by MSD UK Ltd and Eisai Europe Ltd. It is intended to be provided to patients who have been prescribed pembrolizumab in combination with lenvatinib for advanced kidney cancer. This material is not a replacement for the Patient Information Leaflet (PIL), which for your pembrolizumab treatment will be given to you by your doctor, and for your lenvatinib treatment can be found within your prescription box. Please refer to the PIL for full information about potential adverse events.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet (PIL). By reporting side effects, you can help provide more information on the safety of this medicine. You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.



What you need to remember

Your healthcare team should have provided you with materials to help you identify any side effects you may experience during your treatment. This booklet is designed to support that information.

Tell your healthcare professional immediately about any changes to how you are feeling. Do not attempt to diagnose or treat side effects yourself. Reporting side effects early may stop them from becoming more serious and can make them easier to treat. They may be managed without having to permanently come off treatment and your healthcare professional will be able to better support you.



Ensure you read the Patient Safety Information Brochure. Keep the pembrolizumab Patient Alert Card with you at all times and show it to any healthcare professional who treats you.



Ensure you read the Patient Information Leaflets (PILs). Use the diary in this book to keep track of how you are feeling and to record any questions you have for your healthcare professional.

If you live in Great Britain, scan the QR codes below to access the PILs



Pembrolizumab



Lenvatinib

If you live in Northern Ireland, scan the QR codes below to access the PILs



Pembrolizumab



Lenvatinib

Important contact details

My details

Name:

Telephone:

Mobile:

My GP details

Name of GP:

Name of surgery:

Surgery telephone:

My hospital details

Hospital name:

Consultant name:

Specialist nurse name:

Hospital telephone:

Acute Oncology Service (AOS) telephone:

My main healthcare team contact is

Name of main contact:

Telephone:

Alternatively, you can place a sticker with your hospital's details over this section.

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SHARE

CARE

Introduction

Purpose of this booklet

Your doctor has prescribed you pembrolizumab and lenvatinib because you have a condition called advanced renal cell carcinoma (aRCC), a type of kidney cancer. This booklet is designed to support you whilst you are receiving treatment for your kidney cancer.

Like with any medicine, you may get side effects from taking pembrolizumab and lenvatinib. It is important to tell your healthcare team as soon as you notice any changes to your body, or how you are feeling, as this might be due to a side effect from your treatment. The earlier you do this, the more likely it is that they can help you manage any side effects or stop them getting worse so you can continue with your treatment.

This booklet will help you to:

- **PREPARE** for your treatment with pembrolizumab and lenvatinib for advanced kidney cancer
- SHARE details of any side effects you might experience with your healthcare team
- CARE for yourself by following your healthcare team's advice and tracking your treatment, food, sleep and side effects using the diary pages

DO NOT ATTEMPT TO DIAGNOSE OR TREAT SIDE EFFECTS BY YOURSELF.

If you have any questions that are not covered in this booklet, please talk to your healthcare team.

If any of the words in this guide are new or difficult to understand, then please see the glossary on page 52. Otherwise, please speak to your healthcare team and they will be able to talk through anything you do not understand.

How should I take pembrolizumab and lenvatinib?

Pembrolizumab¹



Your pembrolizumab treatment will be given to you under the supervision of an experienced healthcare professional. They will give you your treatment through an infusion into a vein, known as an IV infusion, which will take about 30 minutes.



You will get an infusion every 3 or 6 weeks, depending on your treatment schedule. Your healthcare team will decide how many treatments and how often you need them.

It is important that you visit your healthcare team for your scheduled appointments so that they can check your progress and give you your treatment.



If you can't make it to an appointment, call your healthcare team right away to reschedule (don't forget to fill in your healthcare team contact details on page 4 of this booklet so you can contact them more easily).



Your healthcare team will have provided you with a Patient Information Brochure and Patient Alert Card. Please always refer to these first when looking for information on your treatment.

Lenvatinib²

- You should take your lenvatinib dose once each day
- You should try and take your lenvatinib capsules at the same time each day
- You should swallow each capsule whole with water, with or without food. If you have difficulties swallowing lenvatinib capsules, please refer to the Patient Information Leaflet for other ways to take lenvatinib.

Your healthcare professional will tell you how much lenvatinib to take and when to take it. If you have side effects your healthcare professional may need to adjust the dose to suit you - this might mean that your lenvatinib dose is reduced or lenvatinib treatment is paused for a while. If the side effects are not controlled your treatment may be stopped completely. This is why it is important to speak to your healthcare team about side effects.

You should keep lenvatinib in the original blister pack to help protect the medicine from moisture, and do not store it anywhere that is above 25°C. It is very important that you take lenvatinib exactly as you have been told to by your doctor.



Do not take a double amount of lenvatinib (two doses at a time) if you have forgotten the previous dose! If you have taken more lenvatinib than you should, **please talk to a doctor or pharmacist straight away.** It's best to take the lenvatinib package and package insert with you.



PREPARE for your treatment with pembrolizumab and lenvatinib for advanced kidney cancer

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You might start your treatment very quickly after your diagnosis and your healthcare team will give you all the information that you need. In the meantime, this section of the booklet will help you prepare for taking your pembrolizumab and lenvatinib treatments. It includes information on what you can do before starting your treatment.

How can I prepare for my appointment?

Before each of your appointments, you can use this checklist to help you to prepare:



Bring this booklet with you so that you can share your diary with your healthcare team



Write down any questions you might have – you can do this in your treatment diary starting on page 34



Ask a family member or friend to come with you to help you take notes and remember things that your healthcare team have told you



Go for a short walk or do something you enjoy before the appointment to help you gather your thoughts



Try to arrive early to the appointment so that you can take your time

Is there anything I can do before my treatment starts?

Living a healthy lifestyle is something we should all aim for, but if you have a condition like kidney cancer, it is especially important. Even making small changes like doing some light exercise or eating more healthy foods can improve how you are feeling and have health benefits.³

The most effective lifestyle changes are the ones that you stick with. This is why it is important that any changes you make are small and are things that you enjoy and find easy to keep doing.



Cancer treatments or their side effects could cause a change in your weight. If you are worried about losing or gaining weight, talk to your healthcare team who may be able to refer you to a dietitian.⁴



A healthy diet could make you feel better, give you more energy, help you to keep up your strength and may help stop you getting infections.³ The tips below can help you to create a healthy and balanced meal plan, but speak to your healthcare team if you are unsure of how to do this:

- Lower the amount of salt in your diet too much salt can put a strain on your kidneys and is not good for your heart⁵
- A high protein diet has been linked to kidney cancer, and kidney disease in general, so try not to eat too many high protein foods, such as:⁵
 - Meat and fish
 - Eggs
 - Cheese, butter and milk
 - Beans and lentils
- Try to eat more fruit and vegetables rather than more protein⁵
- Heavy drinking can cause kidney damage, so cutting down or stopping drinking alcohol is recommended⁵



Being active can make you feel better because of the release of hormones that make you feel good (endorphins) and it can help with managing your weight and keeping you strong.³ Staying active can also help boost your energy levels and build a routine, which can help you prepare for some possible side effects from your treatment, such as tiredness.³

Being active doesn't have to mean running marathons; even 30 minutes of moderate activity, such as walking or housework, can help boost your fitness and energy levels.³ Going on walks is a good, low-impact way of keeping fit. It is also something that can easily be built into an everyday routine. You can start by making small changes to your day. This could be parking a little further away from the shops or taking the stairs instead of the lift. It can also be something you can enjoy with friends and family by going on longer walks.



If you smoke, you should try to stop.⁵ Smoking has been linked to kidney cancer and many other cancers.⁵ Giving up smoking can be very difficult, especially if you have smoked for years.⁵ You will need a lot of will power and support from your friends and family, but it will be worth it.⁵

Please speak with your doctor or nurse for advice on stopping smoking

Before carrying on with, or starting, any kind of exercise, it is important to speak with your healthcare team and get advice on what would be best for you.



SHARE details of any side effects with your healthcare team

What is a side effect?

Like all medicines, pembrolizumab and lenvatinib can cause side effects. Side effects are symptoms you may get when taking a medicine. The Patient Information Leaflet lists the side effects you may experience. It is unlikely that you will get all of these side effects but most patients will experience at least one. The fact that your doctor has prescribed pembrolizumab and lenvatinib for you means that they believe the benefits of taking this treatment are bigger than the risk of potential side effects.

The importance of reporting side effects

Although not everybody gets them, it is important to look out for any signs and/or symptoms. Whilst side effects may occur soon after starting treatment, be aware that some may occur long after receiving the final dose.

If you notice any symptoms while receiving your treatment, you should speak to your healthcare professional right away – **telling your healthcare professional IMMEDIATELY** once you notice any symptoms may stop them from becoming more serious. Do NOT wait for your next appointment. **Reporting side effects early can make them easier to treat**.

Not all side effects can be easily recognised, but knowing what side effects are possible with your treatment can help you to notice them when they happen. For this reason, you should familiarise yourself with the Patient Information Leaflet (PIL) for pembrolizumab and for lenvatinib, which contains very important information on the side effects you may experience on treatment. You will have received the relevant Patient Information Leaflets from your healthcare professional before starting treatment. If you do not have these leaflets to hand, please ask your healthcare team to provide you with another copy.

Always carry your Patient Alert Card and DON'T ATTEMPT TO DIAGNOSE OR TREAT SIDE EFFECTS BY YOURSELF. Be aware of possible side effects with pembrolizumab and lenvatinib



Refer to the Patient Information Leaflet for pembrolizumab (available at: www.medicines.org.uk/ emc/product/2498/pil) and lenvatinib (available at: www.medicines.org.uk/emc/product/7380/pil) for full information on all potential side effects, including serious side effects. Contact your healthcare professional immediately about any changes to how you are feeling.

What should I tell my doctor if I think I am having side effects?

When sharing your potential side effect with your doctor, you should remember to:

- Be open with your healthcare team about any concerns you have with your disease, symptoms or treatment; they will be there to listen to you and address your concerns
- Write down any questions as you think of them so you remember them later
- If possible, take someone with you to appointments so they can help you to ask questions and remember the answers
- · Ask your healthcare professional to explain things if you need them to
- · Remember that there is support available, so do ask for help if you need it

Having a side effect from your treatment does not always mean that you have to stop or change treatment. Speak with your doctor to agree the best way to manage any side effects you might have. You should always follow advice from your healthcare team.

How do I record my side effects?



You may find it helpful to write down details about your side effects in a diary to help you talk about them with your healthcare team. Writing down the time that you take your treatment and the time that your side effect starts can also help the healthcare team figure out how the treatment is affecting you and come up with a plan to manage your side effects.

You can use the **treatment and side effect diary** on **page 34** of this booklet to help keep track.

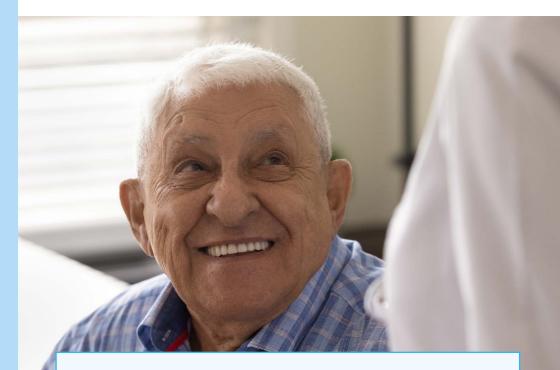


CARE for yourself by following your healthcare team's advice to help manage your treatment and any side effects

Coping with cancer

Everyone reacts differently when they have cancer and you will probably go through a range of emotions after an advanced kidney cancer diagnosis. It is important to remember that there is no 'right' way to react to a diagnosis and that you are not alone.

Your healthcare team is always available to support you. Page 26 includes some other resources that you may find useful if you need further support beyond your healthcare team, family and friends.



You may also find it helpful to visit a local support centre, where you can talk to someone outside your family and friends and they can also provide you with practical advice. Contact your healthcare team if you need help finding your local support centre.

Frequently asked questions

This section answers some of the questions you might have about your treatment. It is a good idea to write down any other questions you have in your Treatment Diary so that you can ask your healthcare professional at your next appointment.

What do I do if I forget to take lenvatinib?

If you forget to take your lenvatinib capsules, do not worry as there are a number of things you can do:²

- If you have 12 hours or more until you need to take your next dose, then take the dose you missed as soon as you remember and take your next dose at the normal time
- If you have less than 12 hours until your next dose, then skip the dose you missed and take your next dose at the normal time
- DO NOT take an extra dose to make up for the one you have missed
- If you take more lenvatinib than you should, please contact your healthcare team or nearest hospital immediately and take the medicine pack with you if you can

How long will I take pembrolizumab and lenvatinib for?

Your healthcare team will let you know how long they think you will need to take your treatment for.

How long will I have side effects for?

This will depend on what side effect you have and whether it is caused by your treatment. When you let your healthcare team know about any side effects, they will help you to manage them. What effect will pembrolizumab + lenvatinib have on my other medicines?

Your treatment may interact with other medicines. It is important to tell your healthcare professional about any medicines you are currently taking or are planning to take, whether they are prescription medicines or those that you buy over the counter.

Can I take vitamins or herbal supplements?

You should tell your healthcare professional about any other medicines, supplements or herbal remedies that you are currently taking or are planning to take. Your healthcare professional can help you to decide if they are suitable to take or not.

Can I have vaccinations?

Consult your healthcare professional before receiving any vaccinations, including the flu vaccination.

Can I go on holiday?

Discuss your holiday plans with your healthcare professional before you book your holiday. Some extra preparation may be necessary, and you should always carry your Patient Alert Card with you.

Can I drink alcohol?

Ideally, when undergoing treatment for cancer, reduce alcohol consumption as much as possible. Your healthcare professional will be able to advise you on this topic.

Why does my blood pressure need to be monitored during treatment?

It is important to monitor your blood pressure, as it may be affected by lenvatinib.² You may have your blood pressure monitored regularly at your clinic or your doctor may ask you to measure it yourself at home. If your blood pressure is consistently increased, your doctor may need to give you medicine to lower it.

Can I drive and/or operate machinery?

You may feel dizzy, tired or weak while taking pembrolizumab + lenvatinib, which can affect your ability to drive or use tools or machines.^{1,2} If this happens, please avoid these activities.



Cancer Research UK www.cancerresearchuk.org

Nurse helpline: 0808 800 4040



Macmillan Cancer Support www.macmillan.org.uk

Helpline: 0808 808 00 00



Kidney Cancer UK www.kcuk.org.uk

Support line: 0800 002 9002



Action Kidney Cancer www.actionkidneycancer.org Helpline: 0800 121 8721

These organisations are independent patient support groups; MSD and Eisai are not responsible for the content of their websites. The organisations have not been involved in the development of this booklet.

Advice from my healthcare team

Your healthcare team will be able to give you advice about your treatment and managing any side effects. You can use this page to list any important information that they share with you that you would like to remember.

Advice from my	healthcare team	

Keeping track of your treatment, food, sleep and side effects

You can use this diary to keep a record of your treatment with pembrolizumab and lenvatinib, and also track your food and sleep to see how they affect your health. The diary includes sections about using the medicine itself (e.g., side effects that you experience, any difficulties you might have with taking the medication), as well as other parts of your life that could be impacted during treatment (e.g., activities such as work or your social life).

It is important to tell your healthcare professional immediately about any side effects. You can use this diary when you call or visit your healthcare team, but do not wait for your next appointment to discuss new symptoms.

Bring this diary to every meeting you have with a member of your cancer care team as it will help you talk through how you have been feeling and help them manage any difficulties you may be experiencing. Don't forget to ask your doctor or nurse for another copy of this booklet once you've finished this diary.

We hope this booklet will be useful for you and remember that your healthcare team are always the best people to go to if you have questions. They know about your medical history and the treatments you are taking and are best placed to give you advice.

Treatment tracker

Use this page to note down the dose and timing of your pembrolizumab and lenvatinib treatments and track any changes to your daily dose of lenvatinib. There is also space for adding any other treatments that you take so you have all the information you need in one place.

Treatment	How much do you take?	How often do you take it?
Pembrolizumab	mg	Every weeks
Lenvatinib	mg	Once a day at:

Lenvatinib dose changes

Date	New dose
	mg
	mg
	mg

Appointment details

You can use this page to keep track of any appointments you have and write down any important information that you are told during your appointment (e.g., changes in treatment, discussions about side effects, advice given by your healthcare team).

Date / time	Questions to ask	Important information

Diary example

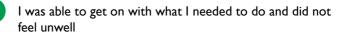
This page shows an example of how you can use this diary. Do not worry if you do not manage to fill it in every day. Even a few days each week can help you and your healthcare team notice any changes to your health and if you need to do anything differently.

Tracking how you feel

3

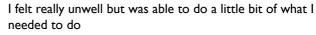
2

Use the guidance below to rate how you felt each day from 1-5.



I was able to cope with my symptoms throughout the day and get on with quite a bit of what I needed to do

I felt quite unwell at times but there were other times when I felt somewhat better and I was able to get on with what I needed to do



I was not able to do anything at all because I was feeling so unwell

Tracking your sleep quality

- I slept really well and did not wake up until morning
- I slept reasonably well but I did not sleep through the whole night
- I slept ok, but I was awake quite a bit too
- I did not sleep well and spent more time awake than asleep
- I slept terribly or do not think I slept at all

Write the date	Monday 6th September
Rate how you feel each day from 1–5 using the guidance on page 32	4
Note any side effects and how you felt	Felt sick and tired
Write any medications you took and when, including medications other than pembrolizumab and lenvatinib	Lenvatinib 20mg/9am
Write what you ate and drank. You can also note how much you managed to eat or any foods you avoided	Plain toast, salad, banana, chicken, rice and peas. Avoided dairy. Drank 6 glasses of water.
Note what you did during the day	Light housework in the morning; managed a walk
Rate how you slept last night using the guidance on page 32	3
Write down how many hours you slept last night, including naps	6 + two half hour naps
Make a note of anything you think might be important during the week:	
 Any patterns of when side effects happened 	Felt sick in the morning again
• How long they lasted	Felt better after a nap and some plain toast
 If anything made you feel better or worse 	Ask nurse about how I can stop feeling sick in the morning
• Any questions you want to ask your healthcare team	
	Rate how you feel each day from 1–5 using the guidance on page 32Note any side effects and how you feltWrite any medications you took and when, including medications other than pembrolizumab and lenvatinibWrite what you ate and drank. You can also note how much you managed to eat or any foods you avoidedNote what you did during the dayRate how you slept last night using the guidance on page 32Write down how many hours you slept last night, including napsMake a note of anything you think might be important during the week:• Any patterns of when side effects happened• How long they lasted • If anything made you feel better or worse• Any questions you want to ask



Date	How I felt today (1–5)	Side effects	Medication /times	Diet	Activities	Sleep rating (1-5)	Sleep hours
Monday							
Tuesday							
Wedne sday							
Thursday							
Friday							
Saturday							
Sunday							
Comm	ents						

and



Date	How I felt today (1–5)	Side effects	Medication /times	Diet	Activities	Sleep rating (1-5)	Sleep hours
Monday							
Tuesday							
Wedne sday							
Thursday							
Friday							
Saturday							
Sunday							
Comm	ents						

and



Date	How I felt today (1–5)	Side effects	Medication /times	Diet	Activities	Sleep rating (1-5)	Sleep hours
Monday							
Tuesday							
Wedne sday							
Thursday							
Friday							
Saturday							
Sunday							
Comm	ents						

and



Date	How I felt today (1–5)	Side effects	Medication /times	Diet	Activities	Sleep rating (1-5)	Sleep hours
Monday							
Tuesday							
Wedne sday							
Thursday							
Friday							
Saturday							
Sunday							
Comm	ents						

and



Date	How I felt today (1–5)	Side effects	Medication /times	Diet	Activities	Sleep rating (1-5)	Sleep hours
Monday							
Tuesday							
Wedne sday							
Thursday							
Friday							
Saturday							
Sunday							
Comm	ents						

and



Date	How I felt today (1–5)	Side effects	Medication /times	Diet	Activities	Sleep rating (1-5)	Sleep hours
Monday							
Tuesday							
Wedne sday							
Thursday							
Friday							
Saturday							
Sunday							
Comm	ents	·					

and



Date	How I felt today (1–5)	Side effects	Medication /times	Diet	Activities	Sleep rating (1-5)	Sleep hours			
Monday										
Tuesday										
Wedne sday										
Thursday										
Friday										
Saturday										
Sunday										
Comments										

and



Date	How I felt today (1–5)	Side effects	Medication /times	Diet	Activities	Sleep rating (1-5)	Sleep hours			
Monday										
Tuesday										
Wedne sday										
Thursday										
Friday										
Saturday										
Sunday										
Comments										

and

Glossary

Abdomen: The part of your body between your chest and pelvis. This is where your stomach, intestines, liver and other organs in your digestive tract are.

Blood vessel: A tube-like structure that carries blood through your tissues and organs.

Growth signals: Molecules that signal between cells and encourage them to grow.

Healthcare team: The people who are responsible for your health. Your healthcare team includes your oncologists, nurses, pharmacists and GP (your general practitioner, or family doctor).

Immune system: The organs and cells within your body that help protect you from harmful things like infections, and help your body heal after an injury.

Immunotherapy: A type of treatment that helps cells in your immune system to recognise and attack cancer cells.

Kidney: The kidneys are two bean-shaped organs that help the body filter waste products and excess water to make urine.

Lenvatinib: This is the generic name of your treatment. The brand name is KISPLYX[®]. It works by stopping growth signals to blood vessels on your tumour, stopping it from receiving what it needs to grow and multiply.² This means the tumour may shrink or stop growing.²

Patient Information Leaflet (PIL): the PIL can be found inside your pack of lenvatinib. The pembrolizumab PIL will be provided to you by the doctor who gives you your pembrolizumab treatment.

Pembrolizumab: This is the generic name of your treatment. The brand name is KEYTRUDA[®]. It is a type of immunotherapy.

Renal cell carcinoma: A type of cancer (carcinoma) that affects the cells in the kidneys (renal).

Side effect: An unwanted or unexpected effect caused by your treatment, for example, feeling tired.

Sleep hygiene: Habits and practices that help you to sleep well on a regular basis.

Treatment diary: A place where you can record your daily habits, any side effects you may have and how they affect you.

References

All URLs were accessed in January 2024.

- I. KEYTRUDA® (pembrolizumab) Patient Information Leaflet. Available at: www.medicines.org.uk/emc/product/2498/pil
- 2 KISPLYX® (lenvatinib) Patient Information Leaflet. Available at: www.medicines.org.uk/emc/product/7380/pil
- 3. Kidney Cancer UK. Lifestyle advice. Available at: www.kcuk.org.uk/patient-support/lifestyle-advice/
- 4. Macmillan Cancer Support. Changes in weight. I August 2020. Available at: www.macmillan.org.uk/cancer-information-and-support/treatment/coping-withtreatment/changes-in-weight
- Cancer Researck UK. Daily life with kidney cancer . 15 June 2020. Available at: <u>https://www.cancerresearchuk.org/about-cancer/kidney-cancer/living-with/daily-life</u>

Please refer to page 3 to scan the QR codes to access the Patient Information Leaflets for pembrolizuab and lenvatinib



PREPARE

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