

EXKIVITY®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using EXKIVITY?

EXKIVITY contains the active ingredient mobocertinib. EXKIVITY is used to treat adult patients with a kind of lung cancer called non-small cell lung cancer (NSCLC) whose tumours have a certain type of abnormal epidermal growth factor receptor (EGFR) gene and, who have received prior platinum-based chemotherapy.

For more information, see Section [1. Why am I using EXKIVITY?](#) in the full CMI.

2. What should I know before I use EXKIVITY?

Do not use if you have ever had an allergic reaction to EXKIVITY or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use EXKIVITY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EXKIVITY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use EXKIVITY?

- The recommended dosage of EXKIVITY is 160 mg orally once daily. EXKIVITY can be taken with or without food. Swallow EXKIVITY capsules whole. Do not open, chew or dissolve the contents of the capsules.
- Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I use EXKIVITY?](#) in the full CMI.

5. What should I know while using EXKIVITY?

Things you should do	<ul style="list-style-type: none">● Remind any doctor or dentist you visit that you are using EXKIVITY. If you become pregnant while using this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">● Do not stop using EXKIVITY or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">● Be careful driving or operating machinery until you know how EXKIVITY affects you.
Looking after your medicine	<ul style="list-style-type: none">● Keep the EXKIVITY in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using EXKIVITY?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include diarrhoea, rash, nausea, mouth sores, vomiting, dry skin, loss of appetite, nail inflammation, tiredness.

Serious side effects include heart problems including abnormal heart beat (electrical activity of your heart called QTc prolongation and Torsades de Pointes) or heart failure, lung problems, diarrhoea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI

- ▼ This medicine is subject to additional monitoring due to provisional approval. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

EXKIVITY®

Active ingredient(s): mobocertinib

This medicine has **provisional approval** in Australia to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC). The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using EXKIVITY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EXKIVITY.**

The information in this leaflet was last updated in July 2022. More recent information on the medicine may be available. You should ensure that you speak to

your pharmacist or doctor to obtain the most up to date information on this medicine.

Where to find information in this leaflet:

- [1. Why am I using EXKIVITY?](#)
- [2. What should I know before I use EXKIVITY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EXKIVITY?](#)
- [5. What should I know while using EXKIVITY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)
8. Instructions for preparing and injecting EXKIVITY

1. Why am I using EXKIVITY?

EXKIVITY contains the active ingredient mobocertinib. EXKIVITY is used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC). It is used if:

- the tumour has a defect (mutation) within the epidermal growth factor receptor (EGFR) gene, and
- it has spread to other parts of the body (metastatic), and
- your previous treatment was a specific type of chemotherapy that contains platinum (e.g., cisplatin or carboplatin).

Your healthcare provider will perform a test to make sure that EXKIVITY is right for you.

2. What should I know before I use EXKIVITY?

Warnings

Do not use EXKIVITY if you:

1. are allergic to mobocertinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have or had any of these medical conditions: lung or breathing problems other than lung cancer; heart problems (including a condition called long QTc syndrome and Torsades de Pointes); problems with your electrolytes (such as sodium, potassium, calcium or magnesium)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. EXKIVITY can harm your unborn baby.

Females who are able to become pregnant:

- Your doctor should do a pregnancy test before you start treatment with EXKIVITY.
- You should use an effective form of non-hormonal birth control during treatment and for 1 month after your last dose of EXKIVITY.
- Birth control pills (oral contraceptives) and other hormonal forms of birth control may not work as well during treatment with EXKIVITY.
- Talk to your doctor about birth control methods that might be right for you during this time.
- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with EXKIVITY.

Males who have female partners who are able to become pregnant:

- You should use effective birth control during treatment and for 1 week after your last dose of EXKIVITY.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by EXKIVITY or may affect how EXKIVITY works. Some examples include:

- ketoconazole, itraconazole, voriconazole, posaconazole, fluconazole: medicines to treat fungal infections
- efavirenz, etravirine, ritonavir, saquinavir, cobicistat: medicines to treat HIV infection
- clarithromycin, ciprofloxacin, erythromycin: medicines to treat bacterial infections
- bosentan, diltiazem, verapamil: medicines to treat irregular heart rhythm and high blood pressure
- St. John's wort: an herbal product used to treat depression. It is also known as hypericum perforatum.
- alfentanil, fentanyl: medicines to treat pain
- modafinil: a medicine to treat excessive sleepiness
- carbamazepine: a medicine to treat epilepsy, euphoric/depressive episodes and certain pain conditions
- phenobarbital, phenytoin, primidone: medicines to treat epilepsy
- rifabutin, rifampicin: medicines to treat tuberculosis or certain other infections
- ciclosporin, sirolimus, tacrolimus: medicines to suppress the immune system
- simvastatin: medicine to treat high cholesterol
- estrogen, progesterones: hormonal birth control such as the pill, the patch, hormone-containing intrauterine device, or vaginal ring
- medicines that prolong the QTc interval: for example, amiodarone, azithromycin, moxifloxacin, ondansetron

Your doctor may have to change your dose of other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

4. How do I use EXKIVITY?

How much to take

- The recommended daily dose is 160 mg (four capsules) taken once per day.
- If you are not sure, ask your doctor or pharmacist for advice.
- Follow the instructions provided and use EXKIVITY until your doctor tells you to stop.

When to take EXKIVITY

- Take EXKIVITY at the same time each day. It is important to take EXKIVITY every day for as long as your doctor tells you to.

How to take EXKIVITY

- EXKIVITY can be taken with or without food. Swallow EXKIVITY capsules whole. Do not open, chew or dissolve the contents of the capsules.
- Avoid eating grapefruit or drinking grapefruit juice during treatment with EXKIVITY. Grapefruit may increase the amount of EXKIVITY in your blood.

If you forget to take EXKIVITY

- EXKIVITY should be used regularly at the same time each day. If you miss or vomit your dose, take the next dose at its scheduled time.

Do not take a double dose to make up for the dose you missed.

If you use too much EXKIVITY

If you think that you have used too much EXKIVITY, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26** in Australia; **0800 POISON** or **0800 764766** in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using EXKIVITY?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using EXKIVITY.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- experience heart problem, including feeling like your heart is pounding or racing, shortness of breath, chest pain, swelling of your ankles and feet, or feeling faint.
- experience lung or breathing problems including shortness of breath or difficulty breathing, cough and/or fever.
- have any loose stools (diarrhoea) or have stools more often than is normal for you
- become pregnant while using this medicine.

Things you should not do

- Do not stop using EXKIVITY or change the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EXKIVITY affects you.

Looking after your medicine

Store it in a cool dry place where the temperature stays below 30°C.

Do not store it in the bathroom or near a sink, or in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• diarrhoea• rash• nausea• mouth sores• vomiting• dry skin• loss of appetite for several days or longer• nail inflammation• tiredness	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Heart problems, including irregular heartbeats and heart failure. EXKIVITY may cause heart problems that may lead to death. Your healthcare provider should check the electrical activity and function of your heart	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>before you start taking EXKIVITY and during treatment as needed. Your doctor should also check electrolytes in your blood. Tell your healthcare provider right away if you have any signs and symptoms of a heart problem, including feeling like your heart is pounding or racing, shortness of breath, chest pain, swelling of your ankles and feet, or feeling faint.</p> <ul style="list-style-type: none"> ● Lung problems. EXKIVITY may cause inflammation of the lungs that can cause death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you develop any new or worsening symptoms, including trouble breathing or shortness of breath, cough, or fever. 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● Diarrhoea. Diarrhoea is common during treatment with EXKIVITY and should be treated right away. Diarrhoea is generally mild to moderate, but may sometimes be severe. You should have medicine to help control diarrhoea (such as loperamide) readily available to begin treatment. Your healthcare provider may also recommend changes to your diet (such as avoiding foods high in carbohydrates) and may tell you to start drinking more fluids. Diarrhoea can cause loss of too much body fluid (dehydration) and kidney problems and your healthcare provider may need to give you fluids and electrolytes to replace body salts. Tell your healthcare provider right away if you have 	

Serious side effects	What to do
<p>any loose stools or have stools more often than is normal for you. In general, the sooner and better diarrhoea is managed, the more likely it will be controlled and tolerable.</p>	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EXKIVITY contains

Active ingredient (main ingredient)	mobocertinib
Other ingredients (inactive ingredients)	gelatin, titanium dioxide and TekPrint SW-9008

Do not take this medicine if you are allergic to any of these ingredients.

What EXKIVITY looks like

EXKIVITY 40 mg capsule (AUST R 370160): White, size 2, imprinted with “MB788” on the cap and “40mg” on the body in black ink.

Each pack contains 112 capsules.

Who distributes EXKIVITY

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney, NSW 2000

Australia

Telephone: 1800 012 612

This leaflet was prepared in July 2022.

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