RETEVMO® Tablets

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 taking RETEVMO?

RETEVMO contains the active ingredient selpercatinib. RETEVMO is used to treat the following cancers caused by an abnormal RET gene - a type of lung cancer (non-small cell lung cancer (NSCLC)) in adults or a rare type of thyroid cancer (medullary thyroid cancer), in adults and adolescents 12 years and older.
For more information, see Section 1. Why am I taking RETEVMO? in the full CMI.

2. What should I know before I take RETEVMO?

Do not take if you have ever had an allergic reaction to RETEVMO 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 take RETEVMO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RETEVMO 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 take RETEVMO?

Your doctor will prescribe the right dose for you. The maximum doses are: 1) for patients with less than 50 kg body weight: 120 mg twice a day; 2) for patients with 50 kg body weight or greater: 160 mg twice a day.

More instructions can be found in Section 4. How do I take RETEVMO? in the full CMI.

5. What should I know while taking RETEVMO?

Things you should do	• You and your partner should use an effective method of birth control (contraception) to avoid becoming pregnant while taking RETEVMO and for at least one week after your final dose. • Tell your doctor straight away if you experience any signs of bleeding or liver problems. • You will need to have regular blood tests, blood pressure checks and ECG testing. • Remind any doctor, dentist or pharmacist you visit that you are using RETEVMO.
Things you should not do	• Do not take RETEVMO to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop taking your medicine, 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 RETEVMO affects you. • RETEVMO may make you feel tired or dizzy.
Looking after your medicine	• Keep your tablets in the original pack until it is time to take them. • This medicine does not require any special storage conditions.

For more information, see Section 5. What should I know while taking RETEVMO? in the full CMI.

6. Are there any side effects?

Potential side effects include swelling, diarrhoea, tiredness, joint and muscle pain, dry mouth, abdominal pain, constipation, rash, nausea, headache, vomiting, dizziness, decreased appetite, fever, inflamed and sore mouth, fluid in the belly, bladder (urinary tract) infections, hair loss. Serious potential side effects include severe or life-threatening inflammation or accumulation of fluid in the lungs, raised liver enzymes, high blood pressure, bleeding, heart rhythm changes, low thyroid hormone levels, severe infection of the lungs (pneumonia), allergic reactions, accumulation of fluid in the lung and in the abdominal area, severe blistering or peeling of the skin.

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. 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.

RETEVMO® Tablets

Active ingredient: *selpercatinib*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I taking RETEVMO?
2. What should I know before I take RETEVMO?
3. What if I am taking other medicines?
4. How do I take RETEVMO?
5. What should I know while taking RETEVMO?
6. Are there any side effects?
7. Product details

1. Why am I taking RETEVMO?

RETEVMO contains the active ingredient selpercatinib. RETEVMO is an anti-cancer prescription medicine.

RETEVMO is used to treat the following cancers, which are caused by abnormal changes in the RET gene:

- **a lung cancer, called non-small cell lung cancer (NSCLC), in adults.**
- **a rare type of thyroid cancer, called medullary thyroid cancer, in adults and adolescents 12 years and older.**

Your doctor will perform a test to check if your cancer has a change in the RET gene to make sure that RETEVMO is right for you.

In patients whose cancer has an altered RET gene, the change in the gene causes the body to make an abnormal RET protein, which can lead to uncontrolled cell growth and cancer. RETEVMO blocks the action of the abnormal RET protein and so may slow or stop the growth of the cancer. It may also help to shrink the cancer.

2. What should I know before I take RETEVMO?

Warnings

Do not take RETEVMO if:

- you are allergic to selpercatinib, 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 liver problems.
- have lung or breathing problems other than lung cancer.
- have high blood pressure.
- have heart problems including a condition called QT prolongation.
- have bleeding problems.
- have a history of kidney problems or low blood pressure as this may increase your risks associated with tumour lysis syndrome (TLS).
- have problems with your thyroid or levels of thyroid hormone.
- take any medicines for any other condition, including prescription, over the counter medicines, vitamins, minerals and herbal supplements.

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

Tell your doctor if you or your partner are pregnant or intend to become pregnant.

- RETEVMO can harm your unborn baby.
- Females who are able to become pregnant should use an effective method of birth control (contraception) to avoid becoming pregnant while taking RETEVMO and for at least one week after your final dose. Your doctor can discuss the risks and benefits involved.
- Males with female partners, who are able to become pregnant, should use effective method of contraception during treatment with RETEVMO and for at least 1 week after the final dose of RETEVMO.

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

- It is not known if RETEVMO passes into your breastmilk.
- Do not breastfeed if you are taking RETEVMO and for at least 1 week after the last dose.

Use in children

RETEVMO is not intended for use by children under the age of:

- 18 years in non-small cell lung cancer.
- 12 years in medullary thyroid cancer.

Use in elderly

RETEVMO may be used in elderly patients aged 65 years and over.

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 interfere with RETEVMO and affect how it works.

Medicines that may <u>increase</u> the effect of RETEVMO include:

- itraconazole, ketoconazole, posaconazole, voriconazole (used to treat fungal infections)
- ritonavir, saquinavir (used to treat HIV infections/AIDS)

Medicines that may <u>reduce</u> the effect of RETEVMO include:

- carbamazepine (used to treat epilepsy, nerve pain, bipolar disorder)
- phenytoin, phenobarbital (used to treat epilepsy)
- rifampicin, rifabutin (used to treat tuberculosis (TB) and some other infections)
- St. John's wort (a herbal product used to treat mild depression and anxiety)

RETEVMO may affect the way some medicines work, including the following:

- medicines that are a substrate of the liver enzyme CYP3A4, for example:
    - midazolam (used for sedation prior surgery)
    - alfentanil (used in anaesthetic procedures)
    - avanafil, vardenafil (used to treat erectile dysfunction)
    - darunavir (used to treat HIV infections)
    - naloxegol (used to treat constipation)
    - simvastatin (used to treat high blood cholesterol)
- medicines that are a substrate of the liver enzyme CYP2C8, for example:
    - enzalutamide, paclitaxel, sorafenib (used to treat different cancers)
    - buprenorphine (used to treat pain or, when combined with another medicine, opiate dependence)
    - selexipag (used to treat hypertension)
    - montelukast (used to treat asthma)
- ranitidine or other H2 blockers (used to treat ulcers and acid reflux).
- omeprazole or other proton pump inhibitors (used to treat heartburn, ulcers, and acid reflux).
- dabigatran (used to treat deep vein thrombosis and clots in lung, and used to prevent stroke)
- digoxin (used to treat heart disorders).
- levothyroxine (used to treat low thyroid levels - hypothyroidism)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RETEVMO.

4. How do I take RETEVMO?

How much to take

Your doctor will prescribe the right dose for you.

The maximum recommended dose is:

- for patients with less than 50 kg body weight: 120 mg twice a day
- for patients with 50 kg body weight or greater: 160 mg twice a day.

Follow the instructions provided and use RETEVMO until your doctor tells you to stop.

Your doctor may have prescribed RETEVMO capsules in the past. The capsule and tablet are the same.

If you get certain side effects while you are taking RETEVMO your doctor may lower your dose or stop treatment temporarily or permanently.

When to take RETEVMO

- RETEVMO is taken twice a day at about the same time every day, preferably in the morning and evening.
- Swallow the tablet whole with a glass of water. Do not chew, crush or split the tablet before swallowing.
- You can take the tablets either with or without food. Please note, if you are also taking omeprazole or other proton pump inhibitors (used to treat heartburn, ulcers, and acid reflux), then take RETEVMO with a full meal.
- If you are also taking ranitidine or other H2 blockers (used to treat ulcers and acid reflux), then take RETEVMO 2 hours before or 10 hours after taking them.
- If you are taking omeprazole or other proton pump inhibitors (used to treat heartburn, ulcers, and acid reflux), then take RETEVMO with a full meal.
- If you are taking antacid containing aluminium, magnesium, calcium, simethicone, or buffered medicines, then take RETEVMO 2 hours before or 2 hours after.

If you forget to take RETEVMO

If you vomit after taking the dose or forget a dose, take your next dose at your usual time. Do not take a double dose to make up for the forgotten or vomited dose.

If you take too much RETEVMO

If you think that you have taken too much RETEVMO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 taking RETEVMO?

Things you should do

RETEVMO may cause inflammation of the lungs. Your doctor will monitor you before and during treatment with RETEVMO for symptoms. Tell your doctor right away if you notice any symptoms of lung problems including breathlessness, cough and raised temperature as your dose may need to be lowered, or treatment paused.

You will have regular blood tests before and during treatment with RETEVMO, to check your liver function and electrolytes (such as sodium, potassium, magnesium and calcium) in your blood.

RETEVMO may result in abnormal ECGs. You will have an ECG taken before and during your treatment with RETEVMO. Tell your doctor if you experience fainting as it may be a symptom of abnormal ECG.

RETEVMO may affect your blood pressure. Your blood pressure will be measured before and during your treatment.

RETEVMO can affect the way your wounds heal. Tell your doctor if you plan to have surgery. You may need to stop taking RETEVMO at least 7 days before your planned surgery and at least 2 weeks after the surgery.

Your doctor will do blood tests to check your thyroid function before and during treatment with RETEVMO. Tell your doctor if you develop signs or symptoms of low thyroid hormone levels such as weight gain, feeling cold, tiredness that worsens or that does not go away and constipation. Your doctor may prescribe you thyroid hormone replacement and/or your treatment with RETEVMO may be paused until your thyroid hormone levels normalise.

Your doctor may do blood tests to check you for tumour lysis syndrome (TLS). TLS is caused by a fast breakdown of cancer cells. It can cause kidney failure, the need for dialysis treatment, and an abnormal heartbeat. Staying well hydrated may help prevent TLS from occurring.

Call your doctor or go to emergency if you develop nausea, vomiting, weakness, swelling, shortness of breath, muscle cramps and seizures during treatment of RETEVMO.

Children and adolescents

RETEVMO may cause irregular hip joint growth or damage in children (less than 18 years of age) called slipped upper femoral epiphysis or slipped capital femoral epiphysis which may require treatment with surgery. If you/your child are under 18 years of age, your doctor may monitor growth during treatment. Tell your doctor if you/your child experience pain in the hip, groin, thigh or knee, have an unexplained limp, or shortening of one leg.

Call your doctor straight away if you:

- experience signs of bleeding (see additional information under Section 6. Are there any side effects?)
- develop symptoms of liver problems (see additional information under Section 6. Are there any side effects?)
- become pregnant while taking this medicine.
  You and your partner should use an effective method of contraception to avoid becoming pregnant while taking RETEVMO and for at least one week after your final dose.

Remind any doctor, dentist or pharmacist you visit that you are using RETEVMO.

Things you should not do

- Do not take RETEVMO to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine, 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 RETEVMO affects you.

RETEVMO may make you feel tired or dizzy.

Looking after your medicine

- Keep your tablets in the original pack until it is time to take them.
- Store below 30°C.

Keep it where young children cannot reach it.

When to discard your medicine

Do not take this medicine if the inner seal is broken or the packaging is torn or shows signs of tampering.

If it is damaged, return it to your pharmacist for safe disposal.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

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
Gastrointestinal related: • diarrhoea • dry mouth • abdominal pain • constipation	**Speak to your doctor if you have any of these less serious side effects and**

Less serious side effects	What to do
• nausea • vomiting • inflamed and sore mouth which may affect inside of the cheeks, gums, tongue, lips and palate (stomatitis) **Metabolism related:** • decreased appetite **Nervous system related:** • headache • dizziness **Skin disorder:** • rash • hair loss **General disorders:** • joint and muscle pain • swelling of your arms, legs, hands or feet (oedema) • tiredness • fever **Infections:** • Bladder (urinary tract) infections. Symptoms may include: o strong and frequent urge to urinate o cloudy o bloody or strong-smelling urine o burning sensation when urinating **Reproductive disorders:** • difficulty getting and keeping an erection (erectile dysfunction)	**they worry you.**

Serious side effects

Serious side effects	What to do
Liver related: • Abnormal liver function blood tests (increased liver enzymes ALT or AST). Symptoms may include: o yellowing of your skin or the white part of your eyes (jaundice) o loss of appetite o nausea or vomiting o dark 'tea-coloured' urine o pain on the upper right side of your stomach area o sleepiness o bleeding or bruising **Thyroid related:** • Low thyroid levels (hypothyroidism). Symptoms may include: o weight gain o feeling cold o tiredness that worsens or that does not go away o constipation **Blood pressure related:** • High blood pressure (hypertension). Symptoms may include: o confusion o dizziness o headaches o chest pain o shortness of breath **Heart related:** • Heart rhythm changes (QT prolongation). Symptoms may include: o loss of consciousness o fainting o dizziness o a change in the way your heart beats (heart palpitations) **Allergy related:** • Symptoms of an allergic reaction may include: o fever, o rash, and o muscle and joint pain. Typically in the first month of treatment. **Infections:** • Severe infection of the lungs (pneumonia). Symptoms may include: o fever and chills o cough with mucous or phlegm o shortness of breath o chest pain while coughing o fast heartbeat o feeling tired or very weak o nausea and vomiting o loss of appetite o body pain	**Tell your doctor if you have any of these serious side effects as you may require medical attention.**

Serious side effects	What to do
Musculoskeletal related: • Irregular hip joint growth or damage in patients < 18 years of age (slipped upper femoral epiphysis/slipped capital femoral epiphysis). Symptoms may include: o hip, groin, thigh or knee pain o limp when walking o reduced movement of hip joint o shortening of one leg	
Blood related: • Bleeding problems. Signs may include: o vomiting blood or if your vomit looks like coffee-grounds o coughing up blood or blood clots o unusual vaginal bleeding or menstrual bleeding that is heavier than normal o nose bleeds that happen often o pink or brown urine o red or black (looks like tar) stools o unusual bleeding or bruising of your skin o drowsiness or difficulty being awakened o confusion o headache o change in speech **Lung related:** • Severe or life-threatening inflammation (pneumonitis) or scarring of the lungs. Symptoms may include: o shortness of breath o cough o fever • Accumulation of fluid in the lung. Symptoms may include: o shortness of breath o pressure in the chest **Gastrointestinal related:** • Accumulation of fluid in the abdominal area. Symptoms may include: o weight gain o abdominal pain o shortness of breath **Skin related:** • severe blistering or peeling of the skin (suggestive of a severe skin disorder called Stevens-Johnson syndrome)	**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.**

Elderly patients aged 65 years and older may experience a higher number of side effects.

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

Some side effects (for example, high blood pressure, changes in heart rhythm, low thyroid levels, changes in liver or other enzymes, kidney markers, changes in blood tests (such as electrolyte levels, creatinine, bilirubin) and blood cells levels) can only be found when your doctor does tests from time to time.

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

Reporting side effects

After you have received medical advice for any side effects that 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 RETEVMO contains

Active ingredient (main ingredient)	selpercatinib
Other ingredients (inactive ingredients)	**Tablet core content:** microcrystalline cellulose mannitol croscarmellose sodium hyprolose sodium stearylfumarate **Film-coating** *40 mg film-coating:* polyvinyl alcohol titanium dioxide macrogol 4000 purified talc

	iron oxide black *80 mg, and 120mg film-coating:* polyvinyl alcohol titanium dioxide macrogol 4000 purified talc ferric oxide iron oxide black *160mg film-coating:* polyvinyl alcohol titanium dioxide macrogol 4000 purified talc ferric oxide

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

What RETEVMO looks like

RETEVMO 40 mg is a light grey, round tablet debossed on one side with "5340" and debossed with "Ret 40" on the other side. The diameter of the tablet is approximately 6 mm. (AUST R 466116).

RETEVMO 80 mg is a dark red-purple, round tablet debossed on one side with "6082" and debossed with "Ret 80" on the other side. The diameter of the tablet is approximately 7.3 mm. (AUST R 466128).

RETEVMO 120 mg is a light purple, round tablet debossed on one side with "6120" and debossed with "Ret 120" on the other. The diameter of the tablet is approximately 8.75 mm. (AUST R 466129)

RETEVMO 160 mg is a light pink, round tablet debossed on one side with "5562" and debossed with "Ret 160" on the other. The diameter of the tablet is approximately 9.75 mm. (AUST R 466130)

Who distributes RETEVMO

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street, Sydney, NSW 2000

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If you have any questions about RETEVMO, contact Eli Lilly at 1800 454 559 (Australia) or your healthcare professional for assistance.

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