

FYCOMPA Film-Coated Tablets®

Perampanel (2mg, 4mg, 6mg, 8mg, 10mg, 12mg)

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What *Fycompa* is used for

Fycompa contains a medicine called perampanel. It belongs to a group of medicines called anti epileptics. These medicines are used to treat epilepsy - where someone has repeated fits (seizures). It has been given to you by your doctor to reduce the number of fits that you have.

Fycompa is used in association with other antiepileptic drugs to treat a certain form of epilepsy:

~~In adults, adolescents (people aged 12 years and older), and children (from 4 to 11 years)~~

- It is used to treat fits that affect one part of your brain (called a “partial seizure”).
- These partial seizures may or may not then be followed by a fit affecting all of your brain (called a “secondary generalisation”).

In adults, adolescents (aged 12 years and older), and children (from 7 to 11 years)

- It is also used to treat certain fits that affect all of your brain from the start (called “generalised seizures”) and cause convulsions or staring spells.

How *Fycompa* works

The active substance in *Fycompa*, perampanel, is an anti-epileptic medicine. Epilepsy is caused by excessive electrical activity in the brain. Although the precise mechanism by which *Fycompa* works is not fully understood, it is thought to block the action of the neurotransmitter glutamate. Neurotransmitters are naturally-occurring chemicals in the nervous system that allow nerve cells to

communicate with each other. Glutamate is the main stimulatory neurotransmitter in nerve cells.

Therefore by blocking glutamate’s actions, *Fycompa* is thought to stop epileptic seizures from occurring.

Before you use *Fycompa*

- When you must not use it

Do not take *Fycompa* if you are allergic to perampanel or any of the other ingredients of this medicine as listed in Ingredients- and if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking *Fycompa*.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not stop treatment without first discussing it with your doctor.

- *Fycompa* is not recommended in pregnancy.
- You must use a reliable method of contraception to avoid becoming pregnant while you are being treated with *Fycompa*. You should continue doing this for one month after stopping treatment. Tell your doctor if you are taking hormonal contraceptives. *Fycompa* may make certain hormonal contraceptives such as levonorgestrel less effective. You should use other forms of safe and effective contraception (such as a condom or coil) when taking *Fycompa*. You should also do this for one month after stopping treatment. Discuss with your doctor what may be appropriate contraception for you.

It is not known whether the ingredients of *Fycompa* can pass into breast milk. The doctor will weigh up the benefit and risks to your baby of taking *Fycompa* while you are breastfeeding.

Alcohol

Speak to your doctor before drinking alcohol. Be careful about consuming

alcohol with epilepsy medicines including *Fycompa*.

- Drinking alcohol while taking *Fycompa* can make you less alert and affect your ability to drive or use tools or machines.
- Drinking alcohol while taking *Fycompa* can also make any feelings of anger, confusion or sadness worse.

Fycompa contains lactose

Fycompa contains lactose (a type of sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking *Fycompa* if you have liver problems or moderate or severe kidney problems.

You should not take *Fycompa* if you have serious liver problems or moderate or serious kidney problems.

Cases of increased liver enzymes have been reported in some patients taking *Fycompa* in combination with other antiepileptic drugs.

Before taking this medicine you should tell your doctor if you have a history of alcoholism or drug dependence.

If any of the following happens, talk to your doctor or pharmacist.

- *Fycompa* may make you feel dizzy or sleepy, particularly at the beginning of treatment.
- *Fycompa* may make you more likely to fall over, particularly if you are an older person; this might be due to your illness.
- *Fycompa* may make you aggressive, angry or violent. It may also cause you to have unusual or extreme changes in behaviour or mood, abnormal thinking and/or loss of touch with reality.

A small number of people being treated with anti-epileptics have had thoughts of

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harming or killing themselves. If at any time you have these thoughts, contact your doctor straight away.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) and Stevens - Johnson Syndrome (SJS) have been reported with the use of perampanel.

- DRESS typically, although not exclusively, appears as flu-like symptoms and a rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

- Stevens - Johnson Syndrome (SJS) can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.

If you experience any of the above after taking Fycompa (or you are not sure) talk to your doctor or pharmacist.

If you experience any of the above after taking Fycompa (or you are not sure) talk to your doctor or pharmacist.

Children

Fycompa is not recommended for children aged under 4. The safety and effectiveness are not yet known in children under 4 years of age for partial seizures and under 7 years of age in generalised seizures. Fycompa is not recommended for children aged under 12. The safety and effectiveness are not yet known in this age group.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. Taking Fycompa with certain other medicines may cause side effects or affect how they work. Do not start or stop other medicines without talking to your doctor or pharmacist.

- Other anti-epileptic medicines, such as carbamazepine, oxcarbazepine, and phenytoin that are used to treat fits may affect Fycompa. Tell your doctor if you are taking or have recently taken these medicines as your dose may need to be adjusted.

- Felbamate (a medicine used to treat epilepsy) may also affect Fycompa. Tell your doctor if you are taking or have recently taken this medicine as your dose may need to be adjusted.

- Midazolam (a medicine used to stop prolonged, acute (sudden) convulsive seizures, for sedation and sleep problem) may be affected by Fycompa. Tell your doctor if you are taking midazolam as your dose may need to be adjusted.

- Some other medicines such as rifampicin (a medicine used to treat bacterial infections), hypericum (St.

John's Wort) (a medicine used to treat mild anxiety) and ketoconazole (a medicine used to treat fungal infections) may affect Fycompa. Tell your doctor if you are taking or have recently taken these medicines as your dose may need to be adjusted.

- Hormonal contraceptives (including oral contraceptives, implants, injections and patches)

Tell your doctor if you are taking hormonal contraceptives. Fycompa may make certain hormonal contraceptives such as levonorgestrel less effective. You should use other forms of safe and effective contraception (such as a condom or coil) when taking Fycompa. You should continue doing this for one month after stopping treatment. Discuss with your doctor what may be appropriate contraception for you.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist each time you get a new medicine.

How to use Fycompa

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

understand the instructions on the label, ask your doctor or pharmacist for help.

Adults, adolescents (aged 12 years and older) in treating partial seizures and generalised seizures:
ting partial seizures and generalised seizures:

The usual starting dose is 2 mg once a day before you go to bed.

- Your doctor may increase this in 2 mg steps to a maintenance dose between 4 mg and 12 mg - depending on your response.

Children (from 4 to 11 years of age) weighing 30 kg or more in treating partial seizures:

The usual starting dose is 2 mg once a day before you go to bed.

- Your doctor may increase this in 2 mg steps to a maintenance dose between 4 mg and 8 mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 12 mg/day.

Children (from 4 to 11 years of age) weighing 20 kg and less than 30 kg in treating partial seizures:

The usual starting dose is 1 mg once a day before you go to bed.

- Your doctor may increase this in 1 mg steps to a maintenance dose between 4 mg and 6 mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 8 mg/day.

Children (from 4 to 11 years of age) weighing less than 20 kg in treating partial seizures:

The usual starting dose is 1 mg once a day before you go to bed.

- Your doctor may increase this in 1 mg steps to a maintenance dose between 2 mg and 4 mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 6 mg/day.

Children (from 7 to 11 years of age) weighing 30 kg or more in treating generalised seizures:

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The usual starting dose is 2 mg once a day before you go to bed.

- Your doctor may increase this in 2 mg steps to a maintenance dose between 4 mg and 8 mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 12 mg/day.

Children (from 7 to 11 years of age) weighing 20 kg and less than 30 kg in treating generalised seizures:

The usual starting dose is 1 mg once a day before you go to bed.

- Your doctor may increase this in 1 mg steps to a maintenance dose between 4 mg and 6 mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 8 mg/day.

Children (from 7 to 11 years of age) weighing less than 20 kg in treating generalised seizures:

The usual starting dose is 1 mg once a day before you go to bed.

- Your doctor may increase this in 1 mg steps to a maintenance dose between 2 mg and 4 mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 6 mg/day.

- If you have mild or moderate liver problems, your dose should not be more than 8 mg each day and your dose increases should be at least 2 weeks apart.

- Don't take more *Fycompa* than your doctor has recommended. It may take a few weeks to find the right dose of *Fycompa* for you.

Swallow the tablet whole with a glass of water. You can take *Fycompa* with or without food. Do not chew, crush or split the tablet. The tablets cannot be split accurately as there is no break line. To ensure you get the entire dose, the tablets should be swallowed whole without chewing or crushing.

- When to use it

Use as directed by your doctor or pharmacist.

Don't take more *Fycompa* than your doctor has recommended. It may take a few weeks to find the right dose of *Fycompa* for you.

- How long to use it

Take *Fycompa* for as long as your doctor recommends. Do not stop unless your doctor advises you to. Your doctor may reduce your dose slowly to avoid your fits (seizures) coming back or getting worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you forget to take a tablet, wait until your next dose and then carry on as usual. Do not take a double dose to make up for a forgotten dose.

If you have missed less than 7 days of treatment with *Fycompa*, continue taking your daily tablet as originally instructed by your doctor.

If you have missed more than 7 days of treatment with *Fycompa*, talk to your doctor immediately.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause you to experience confusion, agitation, ~~and~~

aggressive behaviour and depressed level of consciousness.

While you are using it

- Things you must -do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Fycompa*

Tell your doctor immediately if you become pregnant while taking this medication.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Stopping *Fycompa* suddenly can cause serious problems.

Stopping *Fycompa* suddenly can cause you to have seizures more often.

Do not take any new medicines without consulting your doctor.

Do not give *Fycompa* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Do not drive or use machines until you know how *Fycompa* affects you.

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You must talk to your doctor about the effect of your epilepsy on driving and using machines.

- *Fycompa* may make you feel dizzy or sleepy, particularly at the beginning of treatment. If this happens to you, do not drive or use any tools or machines.
- Drinking alcohol while taking *Fycompa* may make these effects worse.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

A small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, contact your doctor straight away.

~~A serious allergic reaction that may affect your skin or other parts of your body such as your liver, kidneys, heart or blood cells. This allergic reaction can be life-threatening and can cause death. Contact your doctor right away if you have skin rash, hives, fever or swollen glands that do not go away, swelling of face, shortness of breath, swelling of the legs, yellowing of the skin or whites of the eyes, or dark urine.~~

Very common (may affect more than 1 user in 10) are:

- feeling dizzy
- feeling sleepy (drowsiness or somnolence).

Common (may affect more than 1 user in 100) are:

- increased or decreased appetite, weight gain
- feeling aggressive, angry, irritable, anxious or confused
- difficulty with walking or other balance problems (ataxia, gait disturbance, balance disorder)
- slow speech (dysarthria)
- blurred vision or double vision (diplopia)
- spinning sensation (vertigo)

- feeling sick (nausea)
- back pain
- feeling very tired (fatigue)
- falling down.

Uncommon (may affect more than 1 user in 1000) are:

- thoughts about harming yourself or ending your own life (suicidal thoughts), tried to end your own life (attempted suicide)
- hallucinations (seeing, hearing or feeling things that are not there)
- Abnormal thinking and/or loss of touch with reality (psychotic disorder)

Not known (the frequency of this side effect cannot be estimated from the available data) are:

- Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement.
- Stevens Johnson syndrome, SJS. This serious skin rash can appear as reddish target like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like/flu-like symptoms.

Stop using *Fycompa* if you develop these symptoms and contact your doctor or seek medical attention immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Fycompa*

- Storage

Keep out of the reach and sight of children.

Do not store *Fycompa* above 30°C

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Film-coated tablet (tablet):

2 mg tablet: Orange, round, biconvex tablet, debossed with €275 on one side and '2' on the other side

4 mg tablet: Red, round, biconvex tablet, debossed with €277 on one side and '4' on the other side

6 mg tablet: Pink, round, biconvex tablet, debossed with €294 on one side and '6' on the other side

8 mg tablet: Purple, round, biconvex tablet, debossed with €295 on one side and '8' on the other side

10 mg tablet: Green, round, biconvex tablet, debossed with €296 on one side and '10' on the other side

12 mg tablet: Blue, round, biconvex tablet, debossed with €297 on one side and '12' on the other side

Ingredients

- Active ingredient
Perampanel

- Inactive ingredients

2 mg tablet Core:
Lactose monohydrate
Low-substituted-hydroxypropyl cellulose
Povidone
Magnesium stearate
Film coating: OPADRY ORANGE (containing)
Hypromellose 2910
Talc
Macrogol 8000
Titanium dioxide
Ferric oxide, yellow
Ferric oxide, red

4 mg tablet Core:

Lactose monohydrate
Low-substituted-hydroxypropyl cellulose
Povidone
Magnesium stearate
Film coating: OPADRY RED (containing)
Hypromellose 2910

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Talc
Macrogol 8000
Titanium dioxide
Ferric oxide, red

6 mg tablet Core:
Lactose monohydrate
Low-substituted-hydroxypropyl cellulose
Povidone
Microcrystalline cellulose
Magnesium stearate
Film coating: OPADRY PINK (containing)
Hypromellose 2910
Talc
Macrogol 8000
Titanium dioxide
Ferric oxide, red

8 mg tablet Core:
Lactose monohydrate
Low-substituted-hydroxypropyl cellulose
Povidone
Microcrystalline cellulose
Magnesium stearate
Film coating: OPADRY PURPLE (containing)
Hypromellose 2910
Talc
Macrogol 8000
Titanium dioxide
Ferric oxide, red
Ferric oxide, black

10 mg tablet Core:
Lactose monohydrate
Low-substituted-hydroxypropyl cellulose
Povidone
Microcrystalline cellulose
Magnesium stearate
Film coating: OPADRY GREEN (containing)
Hypromellose 2910
Talc
Macrogol 8000
Titanium dioxide
Ferric oxide, yellow
FD&C Blue #2 Indigo carmine
aluminium lake

12mg tablet Core:
Lactose monohydrate
Low-substituted-hydroxypropyl cellulose

Povidone
Microcrystalline cellulose
Magnesium stearate
Film coating: OPADRY BLUE (containing)
Hypromellose 2910
Talc
Macrogol 8000
Titanium dioxide
FD&C Blue #2 Indigo carmine
aluminium lake

MAL numbers:

MAL14035002AZ
MAL14035005AZ
MAL14035003AZ
MAL14035001AZ
MAL14035004AZ
MAL14035006AZ

Manufacturer

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Product Registration Holder

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Date of revision

29/9/202027/05/2023

Serial number

NPRA (R1/4) 20102021/206
NPRA (R1/A11) 01102021/021
NPRA (R1/3) 23092020/161

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