Package Leaflet: Information for the patient

Fycompa®
2 mg film-coated tablets

Perampanel Eisai
2 mg film-coated tablets

Perampanel Quantum Pharma
2 mg film-coated tablets

(perampanel)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is available as the above names but will be referred to as Fycompa throughout this leaflet.

Other strengths are also available:
4 mg, 6 mg, 8 mg, 10 mg and 12 mg.

What is in this leaflet:

1. What Fycompa is and what it is used for
2. What you need to know before you take Fycompa
3. How to take Fycompa
4. Possible side effects
5. How to store Fycompa
6. Contents of the pack and other information

1. What Fycompa is and what it 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 certain forms of epilepsy:
In adults, adolescents (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 and 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.

2. What you need to know before you take Fycompa

DO NOT TAKE Fycompa:
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking perampanel.
- If you are allergic to perampanel or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
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. Before taking this medicine you should tell your doctor if you have a history of alcoholism or drug dependence.
Cases of increased liver enzymes have been reported in some patients taking Fycompa in combination with other antiepileptic drugs.
- 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.

If you or your family and/or friends notice any of these reactions, talk to your doctor or pharmacist.

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.

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.

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.

Other medicines and Fycompa
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.

Fycompa with 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.

Pregnancy and breast-feeding
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 breast-feeding.

Driving and using machines
Do not drive or use machines until you know how Fycompa affects you.

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.

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

3. How to take Fycompa

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take
<u>Adults, adolescents (aged 12 years and older) in treating partial seizures and generalised seizures:</u>
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.
- 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.

The following table summarises the recommended doses <u>in treating partial seizures in children 4 to 11 years of age and generalised seizures in children 7 to 11 years of age</u>. More details are provided below the table.

	Children weighing:		
	More than 30 kg	20 kg to less than 30 kg	Less than 20 kg
Recommended starting dose	2 mg/day	1 mg/day	1 mg/day
Recommended maintenance dose	4 - 8 mg/day	4 - 6 mg/day	2 - 4 mg/day
Recommended maximum dose	12 mg/day	8 mg/day	6 mg/day

<u>Children (from 4 to 11 years of age) weighing 30 kg or more in treating partial seizures</u>:
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.
- If you have mild or moderate liver problems, your dose should not be more than 4 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.

<u>Children (from 4 to 11 years of age) weighing 20 kg and less than 30 kg in treating partial seizures</u>:
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.
- If you have mild or moderate liver problems, your dose should not be more than 4 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.

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

Children (from 7 to 11 years of age) weighing 30 kg or more in treating 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 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.
- If you have mild or moderate liver problems, your dose should not be more than 4 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.

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.
- If you have mild or moderate liver problems, your dose should not be more than 4 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.

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 4 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.

How to take
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.

If you take more Fycompa than you should
If you have taken more Fycompa than you should contact your doctor straight away. You may experience confusion, agitation, aggressive behaviour and depressed level of consciousness.

If you forget to take Fycompa
- 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 stop taking Fycompa
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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

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 symptoms.

Stop using perampanel if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.**

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

5. How to store Fycompa

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

If your medicine shows visible signs of deterioration, show it to a pharmacist who will advise you what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fycompa contains
The active substance is perampanel.
Each film-coated tablet contains 2 mg perampanel.

The other ingredients are:
Tablet core:
Lactose monohydrate, low-substituted hydroxypropyl cellulose, povidone K-29/32, magnesium stearate (E470b).

Film coating:
Hypromellose 2910, talc, macrogol 8000, titanium dioxide (E171), colourants*.

*The colourants are:
Ferric Oxide, Yellow (E172), Ferric Oxide, Red (E172).

What Fycompa looks like and contents of the pack
The tablets are round, orange, biconvex, film-coated tablets, marked with E275 on one side and 2 on other side.

Fycompa is available in packs of 7 and 28 film-coated tablets.

Manufacturer
Eisai GmbH, Edmund-Rumpler-Straße 3, 60549 Frankfurt am Main, Germany.

Procured from within the EU by the Product Licence Holder:
Quantum Pharmaceutical, Quantum House, Hobson Industrial Estate, Burnopfield, Co. Durham, NE16 6EA.

Repackaged by:
UAB Actiofarma, Kaunas, Lithuania.

Fycompa® 2 mg film-coated tablets

Perampanel Eisai 2 mg film-coated tablets

Perampanel Quantum Pharma 2 mg film-coated tablets

PL: 21923/0203 POM

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format suitable for you.

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