

1.3.2.2 Proposed Patient Information Leaflet - Clean

Patient Information Leaflet

SCHEDULING STATUS: S5

Fycompa 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg film-coated tablets

Perampanel

Contains sugar (lactose monohydrate 78,5 mg, 157 mg, 151 mg, 149 mg, 147 mg, and 145 mg, respectively)

Read this entire leaflet carefully before you start taking Fycompa

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Fycompa has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 prescribed to you by your doctor to reduce the number of fits that you have.

Fycompa is used alone or in association with other anti-epileptic medicines 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 seizures that affect one part of the brain (called a “partial seizure”).
- These partial seizures may or may not be followed by a seizure affecting all of the 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.

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 Fycompa
- if you are allergic (hypersensitive) to perampanel or any of the other ingredients of Fycompa (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Fycompa:

- if you have liver problems; you should not take Fycompa if you have serious liver problems
- if you have moderate or severe kidney problems; you should not take Fycompa if you have serious kidney problems
- if you have a history of alcoholism or drug dependence
- if you are taking any other anti-epileptic medicines (see “Other medicines and Fycompa”); your doctor may need to monitor your liver function and/or adjust your dose of Fycompa

Take special care with Fycompa:

- if you experience any signs of a serious skin reaction such as Drug Reaction with Eosinophilia and

Systemic Symptoms (DRESS) or Stevens-Johnson Syndrome (SJS); tell your doctor immediately

- 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 start having thoughts of harming or killing yourself (suicide); tell your doctor immediately, as some people being treated with anti-epileptics have had thoughts of harming or killing themselves
- Fycompa may make you aggressive, angry or violent, it may also cause you to have unusual or extreme changes in behaviour or mood; your doctor may need to adjust your dose or discontinue Fycompa
- Fycompa may make you feel dizzy or sleepy; tell your doctor if this happens
- Fycompa may make you more likely to fall over, particularly if you are an older person, this might also be due to your illness; tell your doctor if this happens

Children

Fycompa is not recommended for children aged under 4 years. 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

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional 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.

The following medicines may interact with Fycompa:

- Other anti-epileptic medicines, such as carbamazepine, phenytoin, and oxcarbazepine 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.
- Rifampicin (medicine for TB), 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. Therefore, it is recommended that you use other forms of safe and effective contraception when taking Fycompa and for one month after stopping treatment.

Fycompa with alcohol

Speak to your doctor before drinking alcohol. Be cautious 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 worsen your feelings of anger, confusion and sadness.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please

consult your doctor, pharmacist or other healthcare provider for advice before taking Fycompa.

Do not stop treatment without first discussing it with your doctor.

Fycompa is not recommended for women who are pregnant or plan to become pregnant.

You must use a reliable method of contraception to avoid becoming pregnant while you are being treated with Fycompa and for one month after stopping.

See 'Other medicines and Fycompa' section for advice about contraception.

It is not known whether the ingredients of Fycompa can pass into breast milk. Fycompa is not recommended for women who are breastfeeding their babies.

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 sugar (lactose monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Fycompa.

3. How to take Fycompa

Do not share medicines prescribed for you with any other person.

Always take Fycompa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of Fycompa is too strong or too weak, tell your doctor or pharmacist.

How much to take

Adults, adolescents (aged 12 years and older) in treating 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 dose in 2 mg steps to a maintenance dose of between 4 mg and 12 mg once a day, depending on your response.
- If you have mild or moderate liver problems, your dose should not be more than 8 mg once a day and your dose increases should be at least 2 weeks apart.
- Do not take more Fycompa than your doctor has prescribed. It may take a few weeks to find the right dose of Fycompa for you.

Children in treating partial seizures (children from 4 to 11 years of age) and generalised seizures (children from 7 to 11 years of age):

The following table summarises the recommended doses in treating partial seizures in children 4 to 11 years of age, and generalised seizures in children 7 to 11 years of age. 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

Children weighing 30 kg or more:

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

- Your doctor may increase this dose in 2 mg steps to a maintenance dose of between 4 mg and 8 mg once a day, 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 once a day and your dose increases should be at least 2 weeks apart.

- Do not take more Fycompa than your doctor has prescribed. It may take a few weeks to find the right dose of Fycompa for you.

Children weighing 20 kg and less than 30 kg:

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

- Your doctor may increase this dose in 1 mg steps to a maintenance dose of between 4 mg and 6 mg once a day, 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 once a day and your dose increases should be at least 2 weeks apart.
- Do not take more Fycompa than your doctor has prescribed. It may take a few weeks to find the right dose of Fycompa for you.

Children weighing less than 20 kg:

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

- Your doctor may increase this dose in 1 mg steps to a maintenance dose of between 2 mg and 4 mg once a day, 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 once a day and your dose increases should be at least 2 weeks apart.
- Do not take more Fycompa than your doctor has prescribed. 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. The tablets cannot be split accurately as there is no break line, to ensure that you get the correct dose, do not chew, crush or split the tablet. You can take Fycompa with or without food.

If you take more Fycompa than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take the Fycompa tablets and labelling with you for the doctor to see what you have taken. If you have taken more Fycompa than you should, you could 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 the one you have missed. 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 seizures coming back or getting worse.

4. Possible side effects

Fycompa can cause side effects. Not all side effects reported for Fycompa are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Fycompa, please consult your healthcare provider for advice.

*If any of the following happens, **stop taking Fycompa** and tell your doctor immediately or go to the casualty department at your nearest hospital:*

Signs of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which is also known as drug hypersensitivity syndrome:

- widespread or maculopapular rash (rash characterised by a flat, red area on the skin that is covered with small confluent bumps)
- high body temperature

- blood abnormalities (eosinophilia)
- liver enzyme elevations
- enlarged lymph nodes and other body organs involvement

Signs of Stevens-Johnson syndrome (SJS):

- reddish target-like macules or circular patches often with central blisters on the trunk
- skin peeling
- ulcers of mouth, throat, nose, genitals and eyes
- fever and flu-like symptoms

These effects can appear several weeks after starting treatment with Fycompa.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Fycompa. You may need urgent medical attention or hospitalisation.

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

Frequent side effects:

- feeling dizzy, or sleepy (drowsiness or somnolence)
- decreased or increased appetite, weight gain
- feeling aggressive, angry, irritable, anxious or confused
- slow speech (dysarthria)
- difficulty with walking or other balance problems (ataxia, gait disturbance, balance disorder)
- double vision (diplopia), blurred vision
- spinning sensation (vertigo)
- feeling sick (nausea)
- back pain
- feeling very tired (fatigue)
- falling down

Less frequent side effects:

- thoughts about harming yourself or ending your own life (suicidal thoughts), tried to end your own life (attempted suicide)
- seeing, hearing or feeling things that are not there (hallucinations)

Side effects with unknown frequency:

- Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome
- Stevens-Johnson syndrome (SJS) which is a serious skin rash

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Fycompa.

5. How to store Fycompa

Store all medicines out of reach of children.

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

Store at or below 30 °C.

Keep the blisters in the outer carton until required for use.

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.

6. Contents of the pack and other information

What Fycompa contains

The active substance is perampanel. Each tablet contains 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, or 12 mg perampanel.

The other ingredients are:

Tablet core (2 mg and 4 mg tablets): lactose monohydrate, low-substituted hydroxypropyl cellulose, povidone, magnesium stearate (E470b).

Tablet core (6 mg, 8 mg, 10 mg and 12 mg tablets): lactose monohydrate, low-substituted hydroxypropyl cellulose, povidone, microcrystalline cellulose, magnesium stearate (E470b).

Film coating (2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg tablets): hypromellose 2910, talc, macrogol 8000, titanium dioxide (E171), colourants*.

* The colourants are:

2 mg tablet: ferric oxide yellow (E172), ferric oxide red (E172).

4 mg tablet: ferric oxide red (E172).

6 mg tablet: ferric oxide red (E172).

8 mg tablet: ferric oxide red (E172), ferric oxide black (E172).

10 mg tablet: ferric oxide yellow (E172), FD&C Blue #2 indigo carmine aluminium lake (E132).

12 mg tablet: FD&C Blue #2 indigo carmine aluminium lake (E132).

What Fycompa looks like and contents of the pack

All strengths of Fycompa are round, biconvex film-coated tablets.

2 mg tablet: orange, engraved with 'E275' on one side, and '2' on the other.

4 mg tablet: red, engraved with 'E277' on one side, and '4' on the other.

6 mg tablet: pink, engraved with 'E294' on one side, and '6' on the other.

8 mg tablet: purple, engraved with 'E295' on one side, and '8' on the other.

10 mg tablet: green, engraved with 'E296' on one side, and '10' on the other.

12 mg tablet: blue, engraved with 'E297' on one side, and '12' on the other.

Fycompa is available in clear PVC/ silver aluminium blister strips packed in an outer carton in the following pack sizes:

- 2 mg tablets – 7, 28 and 98 tablets
- 4 mg, 6 mg, 8 mg, 10 mg, 12 mg tablets – 7, 28, 84 and 98 tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Eisai Pharmaceuticals Africa (Pty) Ltd.
2nd Floor, Ballyoaks Office Park,
35 Ballyclare Drive, Bryanston,
Johannesburg, Gauteng, 2191, South Africa
Telephone: +27 10 590 4325
e-mail: EPA-compliance@eisai.co.za

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Fycompa 10 mg: 47/2.5/1200

Fycompa 12 mg: 47/2.5/1201