PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS - 1986

This medicine is to be supplied upon physician's prescription only

Fycompa oral suspension, 0.5 mg/ml
Composition:
Active ingredient: Perampanel (as anhydrous) 0.5 mg/ml
For the full list of ingredients and a list of allergens, see: Section 6, "Additional information".
Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your physician or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is this medicine intended for?

Fycompa in combination with other antiepileptic drugs is intended to treat the following:
- Epilepsy characterized by partial-onset seizures with or without secondarily generalized seizures in adults and in children over 4 years old.
- Generalized idiopathic epilepsy characterized by seizures that affect the entire brain (primary generalized tonic-clonic seizures) in adults and children over 12 years old.

Therapeutic group: Selective non-competitive AMPA receptor antagonist.

Fycompa belongs to a group of anti-epileptic medicines.

These medicines are used to treat epilepsy - a disease characterized by seizures that occur repeatedly.

Fycompa has been given to you as treatment to reduce the frequency of the seizures that you suffer from.

2. Before using the medicine:

Do not use this preparation if:
- You have ever had a severe skin rash or skin peeling, blistering and/or mouth sores after taking Perampanel.
- You are sensitive (allergic) to the active ingredient Perampanel or to any of the additional ingredients that the medicine contains (please see Section 6 - "Additional information").

Special warnings regarding the use of the medicine:
Before treatment with Fycompa, tell your physician if:
- You suffer from liver problems.
- You suffer from moderate or severe kidney problems.
- Do not take **Fycompa** if you suffer from severe liver problems or moderate or severe kidney problems.
- You have a history of alcoholism or drug addiction.
- Cases of increased liver enzymes have been reported in some patients taking **Fycompa** in combination with other anti-epileptic medicines.
- **Fycompa** might make you feel dizzy or sleepy, especially at the beginning of the treatment.
- **Fycompa** might make patients fall more, particularly elderly patients. The falls could be due to your illness.
- **Fycompa** might make patients aggressive, angry, or violent. **Fycompa** might also cause extreme changes in behavior 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.

If one of the above applies to you, contact your physician or pharmacist.
A small number of people treated with anti-epileptics have had thoughts of harming or killing themselves. If you have such thoughts, contact your treating physician immediately!
Serious skin reactions including drug reaction with eosinophilia (the number of white blood cells called eosinophils exceeds 350 cells/mm^3 in the blood), systemic symptoms (DRESS), and Stevens-Johnson Syndrome (SJS) have been reported with the use of **Fycompa**.
- Allergic drug syndrome reaction- DRESS: This syndrome typically, although not exclusively, appears as flu-like symptoms and a rash with high body temperature, high levels of liver enzymes in blood tests, an increase in white blood cells called eosinophils (eosinophilia), and enlarged lymph nodes.
- Stevens-Johnson Syndrome (SJS) can appear initially as reddish patches - spots or circular patches that often appear with blisters in the center of the body. Also, ulcers in the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur.
  These severe skin rashes usually manifest after a fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or may even be fatal.

If you experience any of the abovementioned effects after taking **Fycompa** (or if you are not sure), contact your treating physician.

Children and adolescents:
- This medicine is not intended for children under the age of **4** years for the prevention of epilepsy episodes characterized by seizures that begin on one side of the brain (partial seizures).
- This medicine is not intended for children under the age of **12** years for the prevention of epilepsy episodes characterized by seizures that affect the entire brain (generalized tonic-clonic seizures).

It is not known whether the use of **Fycompa** is safe and effective for partial seizures in children under the age of 4, or for generalized tonic-clonic seizures in children under the age of 12.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your physician or pharmacist. Taking **Fycompa** with certain medicines may cause side effects or alter the effect of those medicines. Do not start or discontinue treatment with other medicines without consulting your physician or pharmacist. This applies in particular if you are taking:
- Additional anti-epileptic medicines that are intended for the treatment of seizures, such as: felbamate, carbamazepine, oxcarbazepine and phenytoin, as these medicines may affect **Fycompa.** Tell your physician if you are taking these medicines since they may need to adjust the dosage.
- Midazolam (a medicine used to stop prolonged, acute [sudden] convulsive seizures, spasmodic attacks, and for sedation and sleep disorders) may be affected by **Fycompa**. Tell your physician if you are taking midazolam, as your dose may need to be adjusted.
- Other medicines such as an antibiotic called rifampicin, a medicine used to treat bacterial infections, Hypericum (St. John's Wort), a medicine used to treat mild to moderate depression and anxiety, Ketoconazole - a medicine used for the treatment of fungal infections. These medicines may affect **Fycompa**. Tell your physician if you are taking or have recently taken these medicines since they may need to adjust the dosage.
- Hormonal contraceptives - **Fycompa** may make hormonal contraceptives (including oral contraceptives, implants, injections, and patches) less effective, such as those that contain a hormone called levonorgestrel. While using **Fycompa**, and for one month after stopping treatment with **Fycompa**, it is recommended to use other methods of contraception (such as a condom or a non-hormonal intrauterine device). Consult your physician regarding the contraceptive suitable for you.

Use of the medicine and food:
Fycompa may be taken with or without food, but it should always be taken the same way. For example, if you decide to take this medicine with food, you should always take the medicine this way.

Use of the medicine and alcohol consumption:
Talk to your treating physician before drinking alcohol. Caution should be taken when consuming alcohol during treatment with anti-epileptics, including **Fycompa**.

Drinking alcohol during treatment with **Fycompa** may make you less alert and affect your ability to drive or operate machinery.

In addition, drinking alcohol during treatment with **Fycompa** may worsen feelings of anger, confusion or sadness.

Pregnancy, breastfeeding and fertility:
If you are pregnant, planning to become pregnant, think you may be pregnant, or breastfeeding, consult your physician before taking this medicine. If you are already receiving treatment with **Fycompa**, do not stop your treatment without first consulting your physician.

It is not recommended to use this medicine during pregnancy.

Use safe and effective forms of contraception (such as a condom or a non-hormonal intrauterine device) during treatment with **Fycompa** and for one month after stopping treatment. Tell your physician if you are taking hormonal contraceptives. **Fycompa** may make certain hormonal contraceptives such as levonorgestrel less effective. Consult your physician regarding the appropriate form of contraception for you.

it is unknown whether the ingredients of the medicine passes into breast milk. Your physician will weigh the benefits against the risks of using **Fycompa** while breastfeeding.

Driving and operating machinery:
Do not drive or operate dangerous machinery during treatment with **Fycompa** until you know how the medicine affects you.

Consult your physician about the effect of epilepsy on your ability to drive or operate dangerous machinery.

Fycompa may cause you to feel dizzy or sleepy, particularly at the beginning of the treatment. Do not drive or operate machinery if you feel this way.

Drinking alcohol during treatment with **Fycompa** will make these effects worse.

Important information about some of the medicine's ingredients

Fycompa contains 175 mg sorbitol (E420) in each mL.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Taking **Fycompa** in combination with other anti-epileptics that contain sorbitol may alter their effect. Tell your physician or pharmacist if you are taking anti-epileptics that contain sorbitol.

Fycompa contains <0.005 mg benzoic acid (E210) and 1.1 mg sodium benzoate (E211) in each mL.

Benzoic acid and sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How should you use the medicine?

Always use according to your physician's instructions. You should check with your physician or pharmacist if you are not sure regarding the dosage and treatment regimen.
The dosage and treatment regimen will be determined only by your physician. The usual acceptable dose is as follows:

Adults, adolescents (aged 12 years and older) in treating partial seizures (which affect one part of the brain) and generalised seizures (which affect the entire brain):
The usual starting dose is 2 mg (4 ml) once a day before you go to bed.
- Your doctor may increase this in 2 mg (4 ml) steps to a maintenance dose between 4 mg (8 ml) and 12 mg (24 ml) 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 in treating partial seizures in children 4 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 (4 ml/day)	1 mg/day (2 ml/day)	1 mg/day (2 ml/day)
Recommended maintenance dose	4 – 8 mg/day (8 – 16 ml/day)	4 – 6 mg/day (8 – 12 ml/day)	2 – 4 mg/day (4 – 8 ml/day)
Recommended maximum dose	12 mg/day (24 ml/day)	8 mg/day (16 ml/day)	6 mg/day (12 ml/day)

Children (from 4 to 11 years of age) weighing 30 kg or more in treating partial seizures:
The usual starting dose is 2 mg (4 ml) once a day before you go to bed.
- Your doctor may increase this in 2 mg (4 ml) steps to a maintenance dose between 4 mg (8 ml) and 8 mg (16 ml) - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 12 mg/day (24 ml/day).
- If you have mild or moderate liver problems, your dose should not be more than 4 mg (8 ml) 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 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 (2 ml) once a day before you go to bed.
- Your doctor may increase this in 1 mg (2 ml) steps to a maintenance dose between 4 mg (8 ml) and 6 mg (12 ml) - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 8 mg/day (16 ml/day).
- If you have mild or moderate liver problems, your dose should not be more than 4 mg (8 ml) 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.

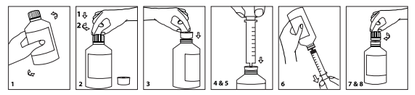
Children (from 4 to 11 years of age) weighing less than 20 kg in treating partial seizures:
The usual starting dose is 1 mg (2 ml) once a day before you go to bed.
- Your doctor may increase this in 1 mg (2 ml) steps to a maintenance dose between 2 mg (4 ml) and 4 mg (8 ml) - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 6 mg/day (12 ml/day).
- If you have mild or moderate liver problems, your dose should not be more than 4 mg (8 ml) 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.

Do not exceed the dose recommended by your physician.
It may take a few weeks to determine the most suitable dosage for you. Switching between the tablet and suspension formulation should be done with caution

Administration route:
Fycompa is for oral use. **Fycompa** oral suspension may be taken with or without food, but it should always be taken the same way. For example, if you decide to take this medicine with food, you should always take the medicine this way.

For dosing, please use the enclosed syringe and adapter.

Instructions for using the syringe and adapter:



1. Shake the bottle for at least 5 seconds before use.
2. To open the bottle, push the cap down (1) and turn (2).
3. Insert the adapter into the bottle neck to create a tight seal.
4. Push the syringe plunger down all the way.
5. Insert the syringe into the adapter opening as far as it goes.
6. Invert the bottle and aspirate the prescribed amount of the medicine.
7. Invert the bottle back and take the syringe out.
8. Leave the adapter in place and replace the bottle cap.
9. After administering the medicine, separate barrel and plunger, and fully immerse these two components in warm soapy water.
10. Immerse the barrel and plunger in water to remove any leftover detergent, shake off any excess water, and leave the two components to air dry. Do not wipe any parts of the syringe dry.
11. Do not reuse the syringe after 40 uses, or if the markings on the syringe are erased or faint.

If you have accidentally taken a higher dosage, you may experience confusion, restlessness, aggressive behavior, and reduced consciousness.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine at the required time, do not take a double dose to make up for the forgotten dose. Take the next dose at the regular time and consult your physician.

Adhere to the treatment regimen as recommended by your physician.

If you forget to take this medicine for less than 7 days, resume treatment as originally instructed by your physician.

If you forget to take this medicine for more than 7 days, contact your physician immediately.

Even if there is an improvement in your health condition, do not stop treatment with this medicine or change the dosage without consulting your physician or pharmacist.

Do not stop taking the medicine unless your physician has told you to stop. Your physician may reduce the dosage of this medicine slowly to prevent your seizures returning or getting worse.

- **Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.**

If you have further questions regarding the use of this medicine, consult your physician or pharmacist.

4. Side effects:

As with any medicine, the use of Fycompa may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

A small number of patients treated with anti-epileptics have had suicidal thoughts or thoughts of harming themselves. **If you have such thoughts, contact your physician immediately!**

<u>Very common side effects (effects that occur in more than one user in 10):</u>
- Dizziness
- Sleepiness or drowsiness

<u>Common side effects (effects that occur in 1-10 in 100 users):</u>
- Increased or decreased appetite, weight gain
- Feelings of aggression, anger, irritability, anxiety or confusion
- Difficulty walking or balance problems (such as coordination disorder, gait disturbance, balance disorder)
- Slow speech
- Blurred vision or double vision
- Dizziness (vertigo)
- Nausea
- Back pain
- Fatigue (tiredness)
- Falling

<u>Uncommon side effects (effects that occur in 1-10 in 1,000 users):</u>
- Suicidal thoughts, thoughts of harming oneself, attempted suicide
- Hallucinations (seeing, hearing, or feeling things that do not exist)
- Abnormal thinking and/or loss of touch with reality (psychotic disorder)

<u>Side effects of unknown frequency (the frequency of these side effects cannot be estimated from the available data):</u>
- Eosinophilia and systemic symptoms, also known as DRESS or drug hypersensitivity syndrome: widespread rash, high body temperature, liver enzyme elevation, blood abnormalities (eosinophilia), enlarged lymph nodes and involvement of other body organs.
- Stevens-Johnson syndrome, SJS: Severe skin rash that can appear as reddish patches: spots or circular patches often with central blisters in the center of the body, skin peeling, ulcers in the mouth, throat, nose, genitals, and eyes; can be preceded by fever and flu-like symptoms.

Stop using **Fycompa** if you develop these symptoms and contact your physician or proceed to a medical center immediately. See also Section 2, "Additional warnings".

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects following Drug Treatment" found on the homepage of the Ministry of Health's website (<u>www.health.gov.il</u>), which directs you to the online form for reporting side effects, or by entering the link: <u>https://sideeffects.health.gov.il</u>

5. How should the medicine be stored?

- Prevent poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants to prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.
- Do not use this medicine after the expiry date (exp. date), which appears on the outer package. The expiry date refers to the last day of that month.

Storage conditions:
- Store at a temperature below 30°C. Do not freeze.
- The medicine can be used within 90 days of opening the bottle, but not later than the expiry date, which appears on the outer package. Do not use the medicine after that.

6. Additional information:

- In addition to the active ingredient Perampanel, this medicine also contains:

sorbitol (E420) liquid (crystallising), microcrystalline cellulose (E460), carmellose sodium (E466), Citric acid, anhydrous (E330), Sodium benzoate (E211), poloxamer 188, simethicone emulsion 30% (containing purified water, silicone oil, polysorbate 65, methylcellulose, silica gel, macrogol stearate, sorbic acid, benzoic acid (E210) and sulfuric acid), and purified water.

What the medicine looks like and what the package contents are:

Fycompa oral suspension is a white to off-white suspension. The suspension comes in a bottle containing 340 ml suspension with 2 syringes and a bottle adapter.

Registration holder and importer: Eisai Israel Ltd., PO Box 8049, Kfar Saba, 4418001, Israel

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Medicine registration number in the Ministry of Health National Drug Registry:
173-16-36621-99