

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

This medicine is dispensed with a physician's prescription only

Fycompa film-coated tablets

2 mg, 4 mg, 6 mg,

8 mg, 10 mg, 12 mg

Film-coated tablets

Composition:

Active ingredient:

Perampanel (as anhydrous)

2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg

Each 2 mg tablet contains 78.5 mg lactose

Each 4 mg tablet contains 157.0 mg lactose

Each 6 mg tablet contains 151.0 mg lactose

Each 8 mg tablet contains 149.0 mg lactose

Each 10 mg tablet contains 147.0 mg lactose

Each 12 mg tablet contains 145.0 mg lactose

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 film-coated tablets is used in association with other antiepileptic drugs.

Fycompa film-coated tablets is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 4 years and older.

Fycompa film-coated tablets is indicated for the adjunctive treatment of primary generalized tonic-clonic seizures in patients with epilepsy aged 12 years and older with idiopathic generalized epilepsy.

Therapeutic group: Selective non-competitive AMPA receptor antagonist.

Fycompa film-coated tablets belong to a group of anti-epileptic medicines.

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

Fycompa film-coated tablets have been given to you as treatment to reduce the frequency of your fits.

2. Before using the medicine:

Do not use this medicine 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:

Serious psychiatric and behavioral reactions may occur during the use of **Fycompa film-coated tablets**:

1. **Fycompa film-coated tablets** may cause mental (psychiatric) problems, including:
 - Worsening of aggressive behavior or new aggressive behavior (including homicidal behavior), hostility, anger, anxiety or irritability
 - Being suspicious or believing things that are not true
 - Seeing objects or hearing things that are not real
 - Confusion
 - Forgetfulness
 - Unusual or extreme changes in behavior or mood.

Inform your physician immediately if you suffer from new mental problems or if mental problems worsen while taking **Fycompa film-coated tablets**.

2. Like other anti-epileptic medicines, the use of **Fycompa film-coated tablets** may cause suicidal thoughts or suicidal actions in a very small number of people, about 1 in 500. Contact your physician immediately if you suffer from any of these symptoms, especially if they are new, worsening, or worry you:
 - Thoughts about suicide or dying
 - Attempt to commit suicide
 - New depression or worsening of depression
 - Emotional outburst or restlessness
 - Panic attacks
 - Trouble sleeping (insomnia)
 - New irritability or worsening of irritability
 - Aggressive, angry or violent behavior
 - Dangerous, impulsive behavior
 - Extreme behavior in activity and talking (mania)
 - Other unusual changes in behavior or mood

Before treatment with Fycompa film-coated tablets, tell your physician if:

- You suffer from liver problems.
- You suffer from moderate or severe kidney problems.
- You have a history of alcoholism or drug addiction.

Additional warnings:

- Cases of increased liver enzymes have been reported in some patients **taking Fycompa film-coated tablets** in combination with other anti-epileptic medicines.
- You may feel dizzy or sleepy, especially at the beginning of the treatment.
- You may fall more due to your illness, especially if you are an older person.
- You may be aggressive, angry or violent. **Fycompa film-coated tablets** may cause extreme changes in behavior or mood.

- A small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves. If you have thoughts of harming or killing yourself, inform your physician immediately!

Serious skin reactions including drug reaction with eosinophilia (the number of white blood cells called eosinophils exceeds 350 cells/mm³ in the blood) and systemic symptoms (DRESS) and Stevens-Johnson Syndrome (SJS) have been reported with the use of **Fycompa film-coated tablets**.

- Drug reaction with eosinophilia and systemic symptoms - 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. Also, ulcers of the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur.
These serious 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 film-coated tablets** (or you are not sure), contact your physician.

Children and adolescents:

- This medicine is not intended for children under the age of **4** years for the prevention of epilepsy characterized by fits 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 characterized by fits that affect the entire brain (generalized tonic-clonic seizures).

It is not known whether **Fycompa film-coated tablets** are safe and effective to use 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. In particular, you should inform your physician or pharmacist if you are taking:

- Additional anti-epileptic medicines that are intended for the treatment of fits, such as: felbamate, carbamazepine, oxcarbazepine and phenytoin, as these medicines may affect **Fycompa film-coated tablets**, and your physician 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 film-coated tablets**. Consult your physician if you are taking midazolam, as your dose may need to be adjusted.
- An antibiotic called rifampicin, used to treat bacterial infections.
- Hypericum (St. John's Wort), a medicine used to treat anxiety.
- Ketoconazole - a medicine used for the treatment of fungal infections.
- Hormonal contraceptives - **Fycompa film-coated tablets** may make hormonal contraceptives (including oral contraceptives, implants, injections, and patches) less effective, especially those that contain a hormone called levonorgestrel. While using **Fycompa film-coated tablets**, and for one month after stopping treatment with **Fycompa film-coated tablets**, it is recommended to use other methods of contraception.

Use of the medicine and food:

The tablet may be swallowed with or without food.

Use of the medicine and alcohol consumption:

During treatment with **Fycompa film-coated tablets**, it is recommended not to consume alcohol. Talk to your physician before drinking alcohol.

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

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

Pregnancy, breastfeeding and fertility:

Pregnancy:

If you are pregnant, planning to become pregnant or think you may be pregnant, ask your physician whether you are allowed to take **Fycompa film-coated tablets**. Do not stop treatment with **Fycompa film-coated tablets** without first consulting your physician. It is not recommended to use this medicine during pregnancy.

While being treated with **Fycompa film-coated tablets** and for one month after stopping treatment – you should use effective contraceptive methods besides hormonal contraceptives, in order to prevent you from getting pregnant during the treatment.

Use safe and effective forms of contraception (such as a condom or a coil) while using **Fycompa film-coated tablets** and for one month after stopping treatment. Consult your physician regarding the appropriate form of contraception for you.

Breastfeeding:

There is insufficient information as to whether the medicine passes into breast milk, so you should discuss this with your physician who will weigh the benefits against the risks of using **Fycompa film-coated tablets** while breastfeeding.

Driving and operating machinery:

Do not drive or operate dangerous machinery during treatment with **Fycompa film-coated tablets** until you know how the medicine affects you, as **Fycompa film-coated tablets** may cause you to feel dizzy or sleepy, particularly at the beginning of the treatment. If this happens to you, do not drive or operate machinery.

Drinking alcohol makes these feelings worse.

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

Important information about some of the medicine's ingredients:

If you have been told that you suffer from an intolerance to certain types of sugars, consult your physician before taking **Fycompa film-coated tablets**, as these tablets contain lactose.

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.

The dosage and treatment regimen will be determined only by your physician.

- **The usual dosage** is generally:

An initial dose of 2 mg once a day at bedtime. Your physician may gradually increase the dosage in 2 mg steps up to a dosage of 4-12 mg, depending on your response to treatment.

Do not exceed the recommended dose.

It may take a few weeks to determine the most suitable dosage for you.

Liver function disturbances:

If you suffer from mild to moderate liver problems, the maximum dosage you will reach should be 8 mg a day and dosage increase should be at least two weeks apart.

Do not take more **Fycompa film-coated tablets** than your physician instructed you. It may take a few weeks until your physician finds the right dose for you.

Crushing / Halving / Chewing:

- Swallow the tablet whole with a glass of water.
- The tablet cannot be halved as it does not have a break line.
- The tablet cannot be chewed or crushed, as it is a film-coated, immediate-release tablet.

If you have accidentally taken a higher dosage, you may experience confusion, emotional outburst or aggressive behavior.

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, talk to 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 slowly to avoid your fits returning or getting worse.

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

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

4. Side effects:

As with any medicine, the use of Fycompa film-coated tablets 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 people treated with anti-epileptics have had thoughts of harming or killing themselves. **If you have such thoughts, contact your physician immediately!**

Very common side effects (effects that occur in more than one user in 10):

- Dizziness, sleepiness

Common side effects (effects that occur in 1-10 in 100 users):

- Increased or decreased appetite, weight gain
- Feelings of aggression, anger, irritability, anxiety or confusion
- Difficulty walking or balance problems (such as ataxia, gait disturbance, balance disorder)

- Slow speech
- Blurred vision or double vision
- Spinning sensation (vertigo)
- Nausea
- Back pain
- Fatigue
- Falling down

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- Suicidal thoughts, attempted suicide

Side effects with unknown frequency (the frequency of these side effects cannot be estimated from the available data):

- 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, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes; can be preceded by fever and flu-like symptoms.
- Problems with muscle coordination, headaches, abdominal pain, injuries

Stop using **Fycompa film-coated tablets** 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 “Report on Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. How should the medicine be stored?

- Avoid 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 in order to avoid 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.

6. Additional information:

- In addition to the active ingredient perampanel, this medicine at the dosages of 2 mg and 4 mg also contains:

lactose monohydrate, low-substituted hydroxypropyl cellulose, povidone, magnesium stearate, hypromellose, talc, macrogol 8000, titanium dioxide, *colourants
- In addition to the active ingredient perampanel, this medicine at the dosages of 6 mg, 8 mg, 10 mg and 12 mg also contains:

lactose monohydrate, low-substituted hydroxypropyl cellulose, povidone, microcrystalline cellulose, magnesium stearate, hypromellose, talc, macrogol 8000, titanium dioxide, *colourants

*colourants:

2 mg: yellow ferric oxide, red ferric oxide

4 mg: red ferric oxide

6 mg: red ferric oxide

8 mg: red ferric oxide, black ferric oxide

10 mg: FD&C blue #2 indigo carmine aluminium lake, yellow ferric oxide

12 mg: FD&C blue #2 indigo carmine aluminium lake

- **What the medicine looks like and contents of the package:**

2 mg: orange, film-coated, round, bevel-edged tablets, marked with E275 on one side and 2 on other side.

4 mg: red, film-coated, round, bevel-edged tablets, marked with E277 on one side and 4 on other side.

6 mg: pink, film-coated, round, bevel-edged tablets, marked with E294 on one side and 6 on other side.

8 mg: purple, film-coated, round, bevel-edged tablets, marked with E295 on one side and 8 on other side.

10 mg: green, film-coated, round, bevel-edged tablets, marked with E296 on one side and 10 on other side.

12 mg: blue, film-coated, round, bevel-edged tablets, marked with E297 on one side and 12 on other side.

2 mg / 4 mg / 6 mg / 8 mg / 10 mg / 12 mg tablets come in blister packs in the following sizes:

7, 10, 14, 28, 84 or 98 tablets

Not all package sizes may be marketed.

- **Registration holder and address:** MegaPharm Ltd., P.O.B. 519, Hod Hasharon 4510501, Israel
- **Manufacturer and address:** Eisai Manufacturing Limited, Hertfordshire, UK
- Reviewed in June 2020
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Fycopma 2 mg film-coated tablets: 150-46-33789

Fycopma 4 mg film-coated tablets: 150-47-33791

Fycopma 6 mg film-coated tablets: 150-48-33792

Fycopma 8 mg film-coated tablets: 150-49-33793

Fycopma 10 mg film-coated tablets: 150-50-33794

Fycopma 12 mg film-coated tablets: 150-51-33795