

Fycompa®

Perampanel (as hemisesquihydrate) film-coated tablet
(per-amp-an-el)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Fycompa.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT FYCOMPA IS USED FOR

Fycompa is used to treat certain forms of epilepsy in people aged 12 years and older.

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

It contains the active ingredient perampanel. Perampanel belongs to

a group of medicines called anti epileptics.

It works by reducing the number of fits that you have.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor’s prescription.

Fycompa has some potential for abuse and misuse and should be used with caution in patients with a history of drug abuse.

There is not enough information to know whether Fycompa would be addictive if abused.

Fycompa should be used with caution in patients aged 65 years or older due to the high rates of dizziness and falls in those patients.

Fycompa should be used with caution in patients with a history of severe mental conditions or aggression.

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

BEFORE YOU TAKE FYCOMPA

When you must not take it

Do not take this medicine if you have an allergy to:

- Perampanel, the active ingredient, or to any of the other ingredients listed at the end of

this leaflet under Product Description

Fycompa contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not give this medicine to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- moderate or severe kidney problems
- history of alcoholism, drug dependence or other psychiatric illness

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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.

If you have not told your doctor about any of the above, tell him/her before you start taking Fycompa.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Fycompa may interfere with each other. These include:

- Carbamazepine, phenytoin, oxcarbazepine
- Rifampicin,
- Hypericum (St. John's wort),
- Felbamate
- Ketoconazole
- Oral contraceptives

These medicines may be affected by Fycompa or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE FYCOMPA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

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

Your doctor may increase the dose in 2 mg steps to a maintenance dose between 4 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.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Fycompa may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full 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 take Fycompa

Take your medicine at about the same time each day before going to bed.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take Fycompa

Continue taking your medicine for as long as your doctor tells you.

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 take it

Wait until your next dose, and then continue to take it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Fycompa. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING FYCOMPA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Fycompa.

Tell any other doctors, dentists and pharmacists who treat you that you are taking Fycompa.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Fycompa.

It may affect other medicines used during surgery.

If you become pregnant while taking Fycompa, tell your doctor immediately.

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

If you are about to have any blood tests, tell your doctor that you are taking Fycompa.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Fycompa to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Serious or life-threatening psychiatric and behavioural adverse reactions including aggression, hostility, irritability, anger, suicidal ideation and homicidal ideation and threats have been reported in patients taking Fycompa.

Patients and caregivers should contact a healthcare provider immediately if any of these reactions or changes in mood, behaviour, or personality that are not typical for the patient are seen while they are taking Fycompa or after stopping Fycompa.

If changes in behaviour or personality are seen notify your doctor immediately. They may reduce your dose of Fycompa or stop treatment with Fycompa.

Patients starting Fycompa should be carefully observed especially when starting treatment and if the dose is increased.

Do not drive or operating machinery 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.

Fycompa may make you more likely to fall over, particularly if you are an older person; this might be due to your illness.

Avoid alcohol while taking Fycompa as it may make these effects worse.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Fycompa

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of 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 or go to accident & emergency straight away.

If you get a skin rash, or fever, and/or enlarged lymph nodes, these could be signs of an allergic reaction. See your doctor immediately as very occasionally this may become serious.

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

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

Common (may affect more than 1 user in 100) side effects 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.

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

- thoughts about harming yourself or ending your own life (suicidal thoughts), tried to end your own life (attempted suicide)
- skin rash
- fever
- enlarged lymph nodes

If you get any side effects, talk to your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING FYCOMPA

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Fycompa or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Fycompa 2 mg film coated tablet is an orange, round, biconvex film-coated tablet, engraved with E275

on one side and 2 on other side. Available in packs of 7.

Fycompa 4 mg film coated tablet is a red, round, biconvex film-coated tablet, engraved with E277 on one side and 4 on other side. Available in packs of 28.

Fycompa 6 mg film coated tablet is a pink, round, biconvex film-coated tablet, engraved with E294 on one side and 6 on other side. Available in packs of 28.

Fycompa 8 mg film coated tablet is a purple, round, biconvex film-coated tablet, engraved with E295 on one side and 8 on other side. Available in packs of 28.

Fycompa 10 mg film coated tablet is a green, round, biconvex film-coated tablet, engraved with E296 on one side and 10 on other side. Available in packs of 28.

Fycompa 12 mg film coated tablet is a blue, round, biconvex film-coated tablet, engraved with E297 on one side and 12 on other side. Available in packs of 28.

Ingredients

Active ingredient:

- Perampanel (as hemisesquihydrate)

Excipient Ingredients:

- lactose,
- hypromellose,
- povidone,
- purified talc,
- magnesium stearate,
- microcrystalline cellulose (6 mg, 8 mg, 10 mg and 12 mg only)
- macrogol 8000,
- titanium dioxide,
- iron oxide yellow (2 mg, 10 mg),
- iron oxide red (2mg, 4 mg, 6 mg, and 8 mg only),
- iron oxide black (8 mg only) and
- Indigo carmine aluminium lake (10 mg & 12 mg only).

This medicine does not contain gluten, tartrazine or any other azo dyes.

SPONSOR

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AUST R 207690

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AUST R 207687

Fycompa 10 mg film coated tablet:
AUST R 207692

Fycompa 12 mg film coated tablet:
AUST R 207691