

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Fycompa 2 mg **perampanel** per film-coated tablet

Fycompa 4 mg **perampanel** per film-coated tablet

Fycompa 6 mg **perampanel** per film-coated tablet

Fycompa 8 mg **perampanel** per film-coated tablet

Fycompa 10 mg **perampanel** per film-coated tablet

Fycompa 12 mg **perampanel** per film-coated tablet

Read this entire leaflet carefully before you start taking Fycompa

- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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.

1. 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 respectively.

The other ingredients are:

Tablet core (2 mg and 4 mg tablets): lactose monohydrate, low-substituted hydroxypropyl cellulose, povidone, magnesium stearate (E572)

Contains sugar (lactose).

Tablet core (6 mg, 8 mg, 10 mg and 12 mg tablets): lactose monohydrate, low-substituted hydroxypropyl

cellulose, povidone, microcrystalline cellulose, magnesium stearate (E572).

Contains sugar (lactose).

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)

2. WHAT FYCOMPA IS USED FOR

Fycompa is used alone or in association with other anti-epileptic medicines to treat certain forms of epilepsy in patients aged 12 years and older.

Fycompa is used to treat seizures that affect one part of the brain (partial seizure). These seizures may or may not be followed by a seizure affecting all of the brain (secondary generalisation).

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.

3. BEFORE YOU TAKE FYCOMPA

Do not take Fycompa if:

If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Fycompa.

You are allergic (hypersensitive) to perampanel or any of the other listed ingredients of Fycompa.

Take special care with Fycompa:

- Fycompa may make you feel dizzy or drowsy.
- Some people being treated with anti-epileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of Fycompa.
 - 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.
- Fycompa contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Fycompa.
- If you have liver or severe kidney problems, talk to your doctor before taking Fycompa. The doctor may decide to give you a reduced dose.
- Fycompa may make you aggressive, angry or violent. It may also cause you to have unusual or extreme changes in behaviour or mood.
- Fycompa may make you more likely to fall over, particularly if you are an older person; this might be due to your illness.
- Before taking Fycompa you should tell your doctor if you have a history of alcoholism or drug dependence.
- Fycompa is not recommended for children under 12 years of age. The safety and effectiveness are not yet known in this age group.

Taking Fycompa with food and drink:

You should take Fycompa when going to bed with a glass of water. Food does not affect the absorption of Fycompa.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare

professional for advice before taking Fycompa.

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.

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

See 'Taking other medicines with Fycompa' section for advice about contraception.

It is not known whether the ingredients of Fycompa can pass into breast milk. Women should not breastfeed their babies while taking Fycompa.

Driving and using machinery:

Fycompa may make you feel dizzy or drowsy, 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.

Don't 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.

Important information about some of the ingredients of Fycompa:

Fycompa contains sugar (lactose). Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take Fycompa.

Taking other medicines with Fycompa:

Always tell your healthcare professional 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, lamotrigine, valproic acid 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.
- Clobazam (medicine used to treat anxiety)
- 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.
- Levodopa (medicine for Parkinson's disease)
- Oral contraceptives

Tell your doctor if you are taking hormonal contraceptives (the Pill). 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.

Drinking alcohol while taking Fycompa can worsen your feelings of anger, confusion and sadness. Be cautious about consuming alcohol with epilepsy medicines including Fycompa. Speak to your doctor before drinking alcohol.

4. 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:

The usual starting dose is 2 mg once a day. Your doctor may increase your dose in 2 mg steps to a dose of 4 mg to 12 mg once a day, depending on your response.

Fycompa should be taken once a day before you go to bed.

If you have liver or severe kidney problems, your doctor may change your dose of Fycompa.

Don't take any 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 breakline, to ensure that you get the correct dose, don't 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 control 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 and aggressive behaviour.

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.

5. 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 doctor, pharmacist or other healthcare professional 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:

- 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

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 (known as DRESS) to Fycompa. You may need urgent medical attention or hospitalisation.

Frequent side effects:

- dizziness, drowsiness
- decreased or increased appetite, weight gain
- aggression, anger, anxiety, irritability, slow speech
- difficulty with balance and posture, gait disturbance
- double vision, blurred vision
- spinning sensation (vertigo)
- feeling sick (nausea)
- back pain

- fatigue
- fall

Less frequent:

- Suicidal ideation (thoughts about how to kill oneself) and suicide attempt

Frequency unknown:

- Acute psychosis (loss of thought and emotions), hallucinations, delusions, paranoia, delirium, confusional state, disorientation, memory impairment

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

6. STORING AND DISPOSING OF FYCOMPA

Keep all medicine out of the 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.

7. PRESENTATION OF FYCOMPA

Fycompa 2 mg - Packs of 7; 28 & 98 tablets in clear PVC/ silver aluminium blisters.

Fycompa 4 mg - Packs of 7, 28; 84 & 98 tablets in clear PVC/ silver aluminium blisters.

Fycompa 6 mg - Packs of 7, 28; 84 & 98 tablets in clear PVC/ silver aluminium blisters.

Fycompa 8 mg - Packs of 7, 28; 84 & 98 tablets in clear PVC/ silver aluminium blisters.

Fycompa 10 mg - Packs of 7, 28; 84 & 98 tablets in clear PVC/ silver aluminium blisters.

Fycompa 12 mg - Packs of 7, 28; 84 & 98 tablets in clear PVC/ silver aluminium blisters.

Blister strips are packed in an outer carton.

Not all pack sizes may be marketed.

8. IDENTIFICATION OF FYCOMPA

2 mg tablet: orange, round, biconvex tablet, engraved with E275 on upper surface and 2 on bottom surface.

4 mg tablet: red, round, biconvex tablet, engraved with E277 on upper surface and 4 on bottom surface.

6 mg tablet: pink, round, biconvex tablet, engraved with E294 on upper surface and 6 on bottom surface.

8 mg tablet: purple, round, biconvex tablet, engraved with E295 on upper surface and 8 on bottom surface.

10 mg tablet: green, round, biconvex tablet, engraved with E296 on upper surface and 10 on bottom surface.

12 mg tablet: blue, round, biconvex tablet, engraved with E297 on upper surface and 12 on bottom surface.

9. REGISTRATION NUMBERS

47/2.5/1196/7/8/9/200/1

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene, Pretoria

Tel no: 012 345 1747

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Registration date: 16 February 2017

Date of latest revision of text: 03 February 2020.

Zambia:

POM

Fycompa 2 mg: 473/001

Fycompa 4 mg: 473/002

Fycompa 6 mg: 473/003

Fycompa 8 mg: 473/004

Zimbabwe:

P.P.

Fycompa 2 mg: 2020/13.1/5988

Fycompa 4 mg: 2020/13.1/5989

Fycompa 6 mg: 2020/13.1/5990

Fycompa 8 mg: 2020/13.1/5991

Namibia:

NS3

Fycompa 2 mg: 20/2.6/0139

Fycompa 4 mg: 20/2.6/0140

Fycompa 6 mg: 20/2.6/0141

Fycompa 8 mg: 20/2.6/0142