

Perampanel Aspire 2mg, 4mg, 6mg, 8mg, 10mg and 12mg film-coated tablets

perampanel

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1 What this medicine is and what it is used for

This medicine contains 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 given to you by your doctor to reduce the number of fits that you have.

This medicine is used in association with other anti-epileptic drugs 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 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").

In adults and 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 this medicine

Do not take this medicine if:

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking perampanel.
- If you are allergic to perampanel or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you have liver problems or moderate or severe kidney problems.

You should not take this medicine if you have serious liver problems or moderate or serious kidney problems.

Before taking this medicine you should tell your doctor if you have a history of alcoholism or drug dependence.

Cases of increased liver enzymes have been reported in some patients taking this medicine in combination with other anti-epileptic drugs.

- This medicine may make you feel dizzy or sleepy, particularly at the beginning of treatment.
- This medicine may make you more likely to fall over, particularly if you are an older person; this might be due to your illness.
- This medicine may make you aggressive, angry or violent. It may also cause you to have unusual or extreme changes in behaviour 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.

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 straight away.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) and Stevens-Johnson Syndrome (SJS) have been reported with the use of perampanel.

- 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 experience any of the above after taking this medicine (or you are not sure) talk to your doctor or pharmacist.

Children

This medicine is not recommended for children aged under 4. 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 Perampanel Aspire

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. Taking this medicine 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.

- Other anti-epileptic medicines, such as carbamazepine, oxcarbazepine, and phenytoin that are used to treat fits may affect this medicine. 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 this medicine. 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 this medicine. Tell your doctor if you are taking midazolam as your dose may need to be adjusted.
- Some other medicines such as rifampicin (a medicine used to treat bacterial infections), hypericum (St. John's Wort) (a medicine used to treat mild anxiety) and ketoconazole (a medicine used to treat fungal infections) may affect this medicine. 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. This medicine 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 this medicine. You should continue doing this for one month after stopping treatment. Discuss with your doctor what may be appropriate contraception for you.

This medicine with alcohol

Speak to your doctor before drinking alcohol. Be careful about consuming alcohol with epilepsy medicines including Perampanel Aspire.

- Drinking alcohol while taking this medicine can make you less alert and affect your ability to drive or use tools or machines.
- Drinking alcohol while taking this medicine can also make any feelings of anger, confusion or sadness worse.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not stop treatment without first discussing it with your doctor.

- This medicine is not recommended in pregnancy.
- You must use a reliable method of contraception to avoid becoming pregnant while you are being treated with this medicine. You should continue doing this for one month after stopping treatment. Tell your doctor if you are taking hormonal contraceptives. This medicine 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 this medicine. 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 this medicine can pass into breast milk.

The doctor will weigh up the benefit and risks to your baby of taking this medicine while you are breast-feeding.

Driving and using machines

Do not drive or use machines until you know how this medicine affects you.

You must talk to your doctor about the effect of your epilepsy on driving and using machines.

- This medicine 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 this medicine may make these effects worse.

This medicine contains lactose

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take this medicine

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take

Adults, adolescents (aged 12 years and older) in treating partial seizures and generalised seizures:

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

- Your doctor may increase this in 2mg steps to a maintenance dose between 4mg and 12mg - depending on your response.
- If you have mild or moderate liver problems, your dose should not be more than 8mg each day and your dose increases should be at least 2 weeks apart.
- Don't take more of this medicine than your doctor has recommended. It may take a few weeks to find the right dose of this medicine for you.

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 30kg | 20kg to less than 30kg | Less than 20kg |
| Recommended starting dose | 2mg/day | 1mg/day | 1mg/day |
| Recommended maintenance dose | 4 - 8mg/day | 4 - 6mg/day | 2 - 4mg/day |
| Recommended maximum dose | 12mg/day | 8mg/day | 6mg/day |

Children (from 4 to 11 years of age) weighing 30kg or more in treating partial seizures:

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

- Your doctor may increase this in 2mg steps to a maintenance dose between 4mg and 8mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 12mg/day.
- If you have mild or moderate liver problems, your dose should not be more than 4mg each day and your dose increases should be at least 2 weeks apart.
- Don't take more of this medicine than your doctor has recommended. It may take a few weeks to find the right dose of this medicine for you.

Children (from 4 to 11 years of age) weighing 20kg and less than 30kg in treating partial seizures:

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

- Your doctor may increase this in 1mg steps to a maintenance dose between 4mg and 6mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 8mg/day.
- If you have mild or moderate liver problems, your dose should not be more than 4mg each day and your dose increases should be at least 2 weeks apart.
- Don't take more of this medicine than your doctor has recommended. It may take a few weeks to find the right dose of this medicine for you.

Children (from 4 to 11 years of age) weighing less than 20kg in treating partial seizures:

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

- Your doctor may increase this in 1mg steps to a maintenance dose between 2mg and 4mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 6mg/day.
- If you have mild or moderate liver problems, your dose should not be more than 4mg each day and your dose increases should be at least 2 weeks apart.
- Don't take more of this medicine than your doctor has recommended. It may take a few weeks to find the right dose of this medicine for you.

Children (from 7 to 11 years of age) weighing 30kg or more in treating generalised seizures:

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

- Your doctor may increase this in 2mg steps to a maintenance dose between 4mg and 8mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 12mg/day.
- If you have mild or moderate liver problems, your dose should not be more than 4mg each day and your dose increases should be at least 2 weeks apart.
- Don't take more of this medicine than your doctor has recommended. It may take a few weeks to find the right dose of this medicine for you.

Children (from 7 to 11 years of age) weighing 20kg and less than 30kg in treating generalised seizures:

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

- Your doctor may increase this in 1mg steps to a maintenance dose between 4mg and 6mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 8mg/day.
- If you have mild or moderate liver problems, your dose should not be more than 4mg each day and your dose increases should be at least 2 weeks apart.
- Don't take more of this medicine than your doctor has recommended. It may take a few weeks to find the right dose of this medicine for you.

Children (from 7 to 11 years of age) weighing less than 20kg in treating generalised seizures:

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

- Your doctor may increase this in 1mg steps to a maintenance dose between 2mg and 4mg - depending on your response. Depending upon individual clinical response and tolerability, the dose may be increased to a maximum dose of 6mg/day.
- If you have mild or moderate liver problems, your dose should not be more than 4mg each day and your dose increases should be at least 2 weeks apart.
- Don't take more of this medicine than your doctor has recommended. It may take a few weeks to find the right dose of this medicine for you.

How to take

Swallow the tablet whole with a glass of water. You can take this medicine with or without food. Do not chew, crush or split the tablet. The tablets cannot be split accurately as there is no break line.

If you take more of this medicine than you should

If you have taken more of this medicine than you should, contact your doctor straight away. You may experience confusion, agitation, aggressive behaviour and depressed level of consciousness.

If you forget to take this medicine

- 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 a forgotten dose.
- If you have missed less than 7 days of treatment with this medicine, continue taking your daily tablet as originally instructed by your doctor.
- If you have missed more than 7 days of treatment with this medicine, talk to your doctor immediately.

If you stop taking this medicine

Take this medicine 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 fits (seizures) coming back or getting worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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 straight away.

Very common (may affect more than 1 in 10 people):

- feeling dizzy
- feeling sleepy (drowsiness or somnolence)

Common (may affect up to 1 in 10 people):

- 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

Uncommon (may affect up to 1 in 100 people):

- thoughts about harming yourself or ending your own life (suicidal thoughts), tried to end your own life (attempted suicide)
- hallucinations (seeing, hearing or feeling things that are not there)
- abnormal thinking and/or loss of touch with reality (psychotic disorder)

Not known (frequency cannot be estimated from the available data):

- Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement.
- Stevens-Johnson syndrome, SJS. This serious skin rash can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms.

Stop using perampanel if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via The Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store this medicine

Keep out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What this medicine contains

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

What this medicine looks like and contents of the pack

Perampanel Aspire 2mg: orange, biconvex, round film-coated tablets, marked with 2 on one side and plain on the other side

Perampanel Aspire 4mg: red, biconvex round film-coated tablets, marked with 4 on one side and plain on the other side

Perampanel Aspire 6mg: pink, biconvex round film-coated tablets, marked with 6 on one side and plain on the other side

Perampanel Aspire 8mg: purple, biconvex, round film-coated tablets, marked with 8 on one side and plain on the other side

Perampanel Aspire 10mg: green, biconvex, round film-coated tablets, marked with 10 on one side and plain on the other side

Perampanel Aspire 12mg: blue, biconvex, oval film-coated tablets, marked with 12 on one side and plain on the other side

Pack sizes: 2mg - pack of 7, 28 and 98 film-coated tablets. 4mg, 6mg, 8mg, 10mg, 12mg – packs of 7, 28, 84 and 98 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

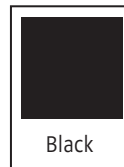
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