

- Changes in the amount of ammonia in the blood. Symptoms of this condition are being sick, problems with balance and co-ordination, feeling lethargic or less alert
- Feeling shaky (tremor), sleepy or unsteady when walking or jerky muscle movements
- Feeling tired or confused with loss of consciousness sometimes accompanied by hallucinations or fits
- Blisters with the skin flaking away
- Rapid, uncontrollable movement of the eyes

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:

- Feeling sick, stomach ache or diarrhoea, especially when starting treatment. This may be helped by taking the tablets with food
- Fainting
- Hearing loss
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine
- Acne
- Hair loss which is usually temporary. When it grows back it may be more curly than before
- Hair, including body or facial hair grows more than normal in women
- Skin rash caused by narrow or blocked blood vessels (vasculitis)
- Changes in women's periods and increased hair growth in women
- Breast enlargement in men
- Swelling of the feet and legs (oedema)
- Weight gain - as your appetite may be increased
- Kidney problems, bedwetting or increased need to pass urine
- Headache
- Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, and learning disorder
- Tingling or numbness in the hands and feet

Bone Disorders

There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.

Blood tests

Epilim can change levels of liver enzymes, salts or sugars shown up on blood and urine tests.

Male Fertility

Taking Epilim can be a contributing factor in male infertility.

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

5. How to store Epilim

Keep out of the reach and sight of children.

Do not take this medicine after the expiry date shown on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not remove the tablets from the foil until just before you take them. Do not cut the blister strips. Store in a dry place below 30°C.

Medicines should not be disposed of via household wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Epilim contains

- Each 200mg gastro-resistant tablet contains 200mg of the active substance, sodium valproate
- Each 500mg gastro-resistant tablet contains 500mg of the active substance, sodium valproate
- The other ingredients are povidone (E1201), talc, calcium silicate (E552), magnesium stearate (E572), hypromellose (E464), citric acid monohydrate (E330), macrogol 6000, polyvinyl acetate phthalate, diethyl phthalate, stearic acid (E570), titanium dioxide (E171), Amaranth aluminium lake (E123), indigo carmine lake (E132) and hydroxypropyl cellulose (E463))

What Epilim looks like and contents of the pack

Epilim tablets are round and lilac coloured. The tablets are supplied in blister packs of 100

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi
One Onslow Street
Guildford
Surrey
GU1 4YS
UK
Tel: 01483 505515
Fax: 01483 535432
email: uk-medicalinformation@sanofi.com

Manufacturer

Fawdon Manufacturing Centre,
Edgefield Avenue
Fawdon
Newcastle-upon-Tyne
Tyne & Wear
NE3 3TT
UK

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in October 2013

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There are two organisations that will also be happy to try and answer any general questions on epilepsy. They can be contacted at:

Epilepsy Action, New Anstey House, Gate Way Drive, Yeadon, Leeds, LS19 7XY
Telephone: 0808 800 5050. Website: www.epilepsy.org.uk

National Society for Epilepsy (NSE), Chesham Lane, Chalfont St Peter, Bucks, SL9 0RJ
Telephone: 01494 601400. Website: www.epilepsynse.org.uk

PACKAGE LEAFLET: INFORMATION FOR THE USER

Epilim® 200mg and 500mg Gastro-resistant Tablets sodium valproate

SANOFI 

 **Is this leaflet hard to see or read?
Phone 01483 505515 for help**

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Epilim is and what it is used for
2. Before you take Epilim
3. How to take Epilim
4. Possible side effects
5. How to store Epilim
6. Further information

1. What Epilim is and what it is used for



What Epilim is

The name of your medicine is Epilim 200mg and 500mg Gastro-resistant Tablets (called Epilim in this leaflet). Epilim 200mg and 500mg Gastro-resistant Tablets are "enteric coated" this means that the tablets have a protective coating that allows it to reach the intestines (gut) without being dissolved in the stomach first. This helps stop it from causing a stomach upset.

What Epilim contains

Epilim contains sodium valproate. It belongs to a group of medicines called anti-convulsants or anti-epileptic agents. It works by helping to calm the brain down.

What Epilim is used for

Epilim is used to treat epilepsy (fits) in adults and children.

2. Before you take Epilim



Do not take Epilim and tell your doctor if:

- × You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of Epilim (see Section 6: Further information)

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- × You have liver problems or you or your family have a history of liver problems
- × You have a rare illness called porphyria

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Epilim.



Take special care with Epilim

A small number of people being treated with anti-epileptics such as sodium valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Check with your doctor or pharmacist before taking this medicine if:

- ▲ You have diabetes. This medicine may affect the results of urine tests
- ▲ You have kidney problems. Your doctor may give you a lower dose
- ▲ You have fits (epilepsy), brain disease or a metabolic condition affecting your brain.
- ▲ You have a 'urea cycle disorder' where too much ammonia builds up in the body.
- ▲ You have an illness called "systemic lupus erythematosus (SLE)" - a disease of the immune system which affects skin, bones, joints and internal organs

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Epilim.

Weight gain

Taking Epilim may make you put on weight. Talk to your doctor about how this will affect you.

Blood tests

Your doctor may wish to do blood tests before you start taking Epilim and during your treatment.



Taking Epilim with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Epilim can affect the way some other medicines work. Also some medicines can affect the way Epilim works.

The following medicines can increase the chance of you getting side effects, when taken with Epilim:

- Some medicines used for pain and inflammation (salicylates) such as aspirin
- Some other medicines used to treat fits (epilepsy) – see page 2, section 3, "Patients taking other medicines for 'fits'". This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, topiramate, lamotrigine and felbamate

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Epilim may increase the effect of the following medicines:

- Medicines used for thinning the blood (such as warfarin)
- Zidovudine used to treat HIV infection
- Temozolomide used to treat cancer
- Medicines for depression
- Monoamine oxidase inhibitors (MAOI) such as moclobemide, selegiline, linezolid
- Medicines used to calm emotional and mental conditions such as diazepam and olanzapine

The following medicines can affect the way Epilim works:

- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine
- Cimetidine used for stomach ulcers
- Carbapenem agents (antibiotics used to treat bacterial infections) such as imipenem, meropenem, rifampicin and erythromycin. The combination of Epilim and carbapenems should be avoided because it may decrease the effect of your medicine.
- Colestyramine used to lower blood fat (cholesterol) levels

Taking Epilim with food and drink

Alcohol intake is not recommended during treatment.

Pregnancy and breast-feeding

Women who could become pregnant

You should not take this medicine if you are pregnant or a woman of child-bearing age unless explicitly advised by your doctor.

Before you start taking Epilim, your doctor should discuss with you the possible problems when it is taken in pregnancy.

- Unplanned pregnancy is not desirable in women taking Epilim
- **You should use an effective method of contraception and talk to your doctor before planning pregnancy.** Epilim has no effect on how well the oral contraceptive pill works.

Well before you become pregnant it is important to discuss pregnancy and epilepsy with your doctor and, if you have one, your epilepsy specialist. This is to make sure that you and your doctor agree that you should have Epilim if you become pregnant.

Women taking Epilim during pregnancy have a higher risk than other women of having a child with an abnormality. The chance of abnormalities is increased if you are also taking other medicines for epilepsy at the same time. These abnormalities include:

- Head and face deformities including cleft palate (a gap or depression in the lip)
- Deformities of the bones, including hip dislocation
- Malformations of the arms and legs
- Deformities of the tubes from the bladder to the penis, where the opening is formed in a different place
- Heart and blood vessel malformations, including heart defects
- Defects of the lining of the spinal cord
- An abnormality of the spinal cord called 'Spina bifida'
- Malformations of the urethra

Women who take Epilim during pregnancy may be more likely to have a baby with spina bifida. **Taking folic acid 5mg each day as soon as you stop contraception may lower the risk of having a baby with spina bifida.**

There is also an increased risk of other birth defects. These other defects can usually be detected in the first 3 months of the pregnancy using routine antenatal screening blood tests and ultrasound scans.

Pregnant mothers who take Epilim may have babies with:

- blood clotting problems (such as blood not clotting or not clotting very well). This may appear as bruising or bleeding which takes a long time to stop.
- Hypoglycaemia (low blood sugar)
- Hypothyroidism (underactive thyroid gland, which can cause tiredness or weight gain).

Some babies born to mothers who took Epilim during pregnancy may develop less quickly than normal or have autistic disorders. These children may require additional educational support.

Talk to your doctor before you stop taking Epilim if you want to become pregnant. Do not stop taking Epilim suddenly, as it is likely that your fits will come back.

Women who are planning to get Pregnant

If you become pregnant, think you may be pregnant or plan to become pregnant while taking Epilim, you must tell your doctor straight away.

- Your doctor will give you appropriate counselling and will suggest changes to your treatment or dose
- He or she will also want to check your progress while you are pregnant

It is very important that you discuss your treatment with your doctor well before you become pregnant.

Breast-feeding

Very little Epilim gets into the breast milk. However, talk to your doctor about whether you should breast-feed your baby. Ask your doctor or pharmacist for advice before taking any medicine.



Driving and using machines:

You may feel sleepy when taking Epilim. If this happens to you, do not drive or use any tools or machines. Taking other medicines used to treat fits or calm emotional and mental health problems may increase sleepiness.

3. How to take Epilim

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

Taking this medicine

- Your doctor will decide how much Epilim to give you or your child depending on your or your child's body weight
- Take this medicine by mouth
- **Do not** crush or chew the tablets
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your doctor

How to take this medicine

- The dose is normally split and given half in the morning and half in the evening

How much to take

Adults (including the elderly)

- The starting dose is 600mg daily. Your doctor should gradually increase this dose by 200mg every 3 days depending on your condition
- The usual dose is between 1000mg and 2000mg (20-30mg per kilogram of body weight) each day
- This may be increased to 2500mg each day depending on your illness

Children over 20 kilograms

- The starting dose should be 400mg daily. Your doctor should increase this dose depending on your child's illness
- The usual dose is then between 20mg and 30mg for each kilogram of body weight each day
- This may be further increased to 35mg for each kilogram of body weight each day depending on your child's illness

Children under 20 kilograms

- The usual dose is 20mg for each kilogram of body weight each day
- Depending on the child's condition your child's doctor may decide to increase the dose

Patients with kidney problems

- Your doctor may decide to adjust your or your child's dose

Patients taking other medicines for 'fits' (epilepsy)

- You or your child may be taking other medicines for epilepsy at the same time as Epilim. If so, your doctor should gradually initiate treatment depending on you or your child's condition
- Your doctor may increase the dose of Epilim by 5 to 10mg for each kilogram of body weight each day depending on which other medicines you are taking

If you take more Epilim than you should

If you take more Epilim than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen: feeling sick or being sick, pupils of the eye become smaller, dizziness, loss of consciousness, weak muscles and poor reflexes, breathing problems, headaches, fits (seizures), confusion, memory loss and unusual or inappropriate behaviour.

If you forget to take Epilim

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Epilim

Keep taking until your doctor tells you to stop. Do not stop taking Epilim just because you feel better. If you stop your fits may come back.

Tests

Make sure you or your child keep your regular appointments for a check up. They are very important as your or your child's dose may need to be changed. Epilim can change the levels of liver enzymes shown up in blood tests. This can mean that your or your child's liver is not working properly.

If you or your child go into hospital or visit another doctor or a dentist, tell them you are taking Epilim.



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

4. Possible side effects

Like all medicines, Epilim can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- You have an allergic reaction. The signs may include: a rash, joint pain, fever (systemic lupus erythematosus), swallowing or breathing problems, swelling of your lips, face, throat or tongue. Hands, feet or genitals may also be affected. More severe allergic reactions can lead to lymph node enlargement and possible impairment of other organs.
- Liver problems and problems of the pancreas may show as a sudden illness which may happen in the first six months of treatment. This happens in a very small number of people taking Epilim. It includes feeling and being sick many times, being very tired, sleepy and weak, stomach pain including very bad upper stomach pain, jaundice (yellowing of the skin or whites of the eyes), loss of appetite, swelling (especially of the legs and feet but may include other parts of the body), worsening of your fits or a general feeling of being unwell. Your doctor may tell you to stop taking Epilim immediately if you have these symptoms
- You have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'
- Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'
- Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called 'Toxic epidermal necrolysis'
- Bruising more easily and getting more infections than usual. This could be a blood problem called 'thrombocytopenia'. It can also be due to a fall in the number of white blood cells, bone marrow depression or another condition that affects red blood cells, white blood cells and platelets (pancytopenia) or how the blood clots
- Blood clotting problems (bleeding for longer than normal), bruising or bleeding for no reason
- Changes in mood, loss of memory, lack of concentration and deep loss of consciousness (coma)
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism)
- Breathing difficulty and pain due to inflammation of the lungs (pleural effusion)

Tell your doctor as soon as possible if you have any of the following side effects:

- Changes in behaviour including being very alert, and sometimes also aggressive, hyper-active and unusual or inappropriate behaviour. This is more likely if other medicine to treat fits such as phenobarbital and topiramate are taken at the same time or if the Epilim starting dose is high or has been suddenly increased

There are two organisations that will also be happy to try and answer any general questions on epilepsy. They can be contacted at:

Epilepsy Action, New Anstey House, Gate Way Drive, Yeadon, Leeds, LS19 7XY
Telephone: 0808 800 5050. Website: www.epilepsy.org.uk

National Society for Epilepsy (NSE), Chesham Lane, Chalfont St Peter, Bucks, SL9 0RJ
Telephone: 01494 601400. Website: www.epilepsynse.org.uk

PACKAGE LEAFLET: INFORMATION FOR THE USER

Epilim® 200mg and 500mg Gastro-resistant Tablets

sodium valproate

SANOFI 

Is this leaflet hard to see or read? Phone 0845 372 7101 for help

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Epilim is and what it is used for
2. Before you take Epilim
3. How to take Epilim
4. Possible side effects
5. How to store Epilim
6. Further information

1. What Epilim is and what it is used for

What Epilim is

The name of your medicine is Epilim 200mg or 500mg Gastro-resistant Tablets (called Epilim in this leaflet). Epilim 200mg or 500mg Gastro-resistant Tablets are “enteric coated” this means that the tablets have a protective coating that allows it to reach the intestines (gut) without being dissolved in the stomach first. This helps stop it from causing a stomach upset.

What Epilim contains

Epilim contains sodium valproate. It belongs to a group of medicines called anti-convulsants or anti-epileptic agents. It works by helping to calm the brain down.

What Epilim is used for

Epilim is used to treat epilepsy (fits) in adults and children.

2. Before you take Epilim



Do not take Epilim and tell your doctor if:

- x You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of Epilim (see Section 6: Further information)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- x You have liver problems or you or your family have a history of liver problems
- x You have a rare illness called porphyria

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Epilim.



Take special care with Epilim

A small number of people being treated with anti-epileptics such as sodium valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Check with your doctor or pharmacist before taking your medicine if:

- ▲ You have diabetes. This medicine may affect the results of urine tests.
- ▲ You have kidney problems. Your doctor may give you a lower dose
- ▲ You have fits (epilepsy), brain disease or a metabolic condition affecting your brain
- ▲ You have a ‘urea cycle disorder’ where too much

- ammonia builds up in the body
- ▲ You have an illness called ‘systemic lupus erythematosus (SLE)’ - a disease of the immune system which affects skin, bones, joints and internal organs

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Epilim.

Weight gain

Taking Epilim may make you put on weight. Talk to your doctor about how this will affect you.

Blood tests

Your doctor may wish to do blood tests before you start taking Epilim and during your treatment.



Taking Epilim Crushable with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Epilim can affect the way some other medicines work. Also some medicines can affect the way Epilim works.

The following medicines can increase the chance of you getting side effects, when taken with Epilim:

- Some medicines used for pain and inflammation (salicylates) such as aspirin
- Some other medicines used to treat fits (epilepsy) – see page 2, section 3, “Patients taking other medicines for ‘fits’”. This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, topiramate, lamotrigine and felbamate

Epilim may increase the effect of the following medicines:

- Medicines used for thinning the blood (such as warfarin)
- Zidovudine - used for HIV infection
- Temozolomide used to treat cancer
- Medicines for depression
- Monoamine oxidase inhibitors (MAOI) such as moclobemide, selegiline, linezolid
- Medicines used to calm emotional and mental conditions such as diazepam and olanzapine

The following medicines can affect the way Epilim works:

- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine
- Cimetidine - used for stomach ulcers
- Carbapenem agents (antibiotics used to treat bacterial infections) such as imipenem, meropenem, rifampicin and erythromycin. The combination of Epilim and carbapenems should be avoided because it may decrease the effect of your medicine
- Colestyramine used to lower blood fat (cholesterol) levels

Taking Epilim with food and drink

Alcohol intake is not recommended during treatment.

Pregnancy and breast-feeding

Women who could become pregnant

You should not take this medicine if you are pregnant or a women of child-bearing age unless explicitly advised by your doctor.

Before you start taking Epilim, your doctor should discuss with you the possible problems when it is taken in pregnancy.

- Unplanned pregnancy is not desirable in women taking Epilim
- **You should use an effective method of contraception and talk to your doctor before planning pregnancy.**
Epilim has no effect on how well the oral contraceptive pill works.

Well before you become pregnant it is important to discuss pregnancy and epilepsy with your doctor and, if you have one, your epilepsy specialist. This is to make sure that you and your doctor agree that you should have Epilim if you become pregnant. Women taking Epilim during pregnancy have a

higher risk than other women of having a child with an abnormality. The chance of abnormalities is increased if you are also taking other medicines for epilepsy at the same time.

These abnormalities include:

- Head and face deformities including cleft palate (a gap or depression in the lip)
- Deformities of the bones, including hip dislocation
- Malformations of the arms and legs
- Deformities of the tube from the bladder to the penis, where the opening is formed in a different place
- Heart and blood vessel malformations, including heart defects
- Defects of the lining of the spinal cord
- An abnormality of the spinal cord called ‘Spina bifida’
- Malformations of the urethra

Women who take Epilim during pregnancy may be more likely to have a baby with spina bifida. **Taking folic acid 5mg each day as soon as you stop contraception may lower the risk of having a baby with spina bifida.**

There is also an increased risk of other birth defects. These other defects can usually be detected in the first 3 months of the pregnancy using routine antenatal screening blood tests and ultrasound scans. Pregnant mothers who take Epilim may have babies with:

- blood clotting problems (such as blood not clotting or not clotting very well). This may appear as bruising or bleeding which takes a long time to stop.
- Hypoglycaemia (low blood sugar)
- Hypothyroidism (underactive thyroid gland, which can cause tiredness or weight gain).

Some babies born to mothers who took Epilim during pregnancy may develop less quickly than normal or have autistic disorders. These children may require additional educational support.

Talk to your doctor before you stop taking Epilim if you want to become pregnant. Do not stop taking Epilim suddenly, as it is likely that your fits will come back.

Women who are planning to get Pregnant

If you become pregnant, think you may be pregnant or plan to become pregnant while taking Epilim, you must tell your doctor straight away.

- Your doctor will give you appropriate counselling and will suggest changes to your treatment or dose
- He or she will also want to check your progress while you are pregnant

It is very important that you discuss your treatment with your doctor well before you become pregnant.

Breast-feeding

Very little Epilim gets into the breast milk. However, talk to your doctor about whether you should breast-feed your baby. Ask your doctor or pharmacist for advice before taking any medicine.



Driving and using machines

You may feel sleepy when taking Epilim. If this happens to you, do not drive or use any tools or machines. Taking other medicines used to treat fits or calm emotional and mental health problems may increase sleepiness.

3. How to take Epilim

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

Taking this medicine

- Your doctor will decide how much Epilim to give you or your child depending on your or your child’s body weight
- Take this medicine by mouth
- **Do not** crush or chew the tablets
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your doctor

How to take this medicine

- The dose is normally split and given half in the morning and half in the evening.

How much to take

Adults (including the elderly)

- The starting dose is 600mg daily. Your doctor should gradually increase this dose by 200mg every 3 days depending on your condition
- The usual dose is between 1000mg and 2000mg (20-30mg per kilogram of body weight) each day
- This may be increased to 2500mg each day depending on your illness

Children over 20 kilograms

- The starting dose should be 400mg daily. Your doctor should increase this dose depending on your child’s illness
- The usual dose is then between 20mg and 30mg for each kilogram of body weight each day
- This may be further increased to 35mg for each kilogram of body weight each day depending on your child’s illness

Children under 20 kilograms

- The usual dose is 20mg for each kilogram of body weight each day
- Depending on the child’s condition your child’s doctor may decide to increase this dose

Patients with kidney problems

- Your doctor may decide to adjust your or your child’s dose

Patients taking other medicines for ‘fits’ (epilepsy)

- You or your child may be taking other medicines for epilepsy at the same time as Epilim. If so, your doctor should gradually initiate treatment depending on you or your child’s condition
- Your doctor may increase the dose of Epilim by 5 to 10mg for each kilogram of body weight each day depending on which other medicines you are taking

If you take more Epilim than you should

If you take more Epilim than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen: feeling sick or being sick, pupils of the eye become smaller, dizziness, loss of consciousness, weak muscles and poor reflexes, breathing problems, headaches, fits (seizures), confusion, memory loss and unusual or inappropriate behaviour.

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If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Epilim

Keep taking until your doctor tells you to stop. Do not stop taking Epilim just because you feel better. If you stop your fits may come back.

Tests

Make sure you or your child keep your regular appointments for a check up. They are very important as your or your child’s dose may need to be changed. Epilim can change the levels of liver enzymes shown up in blood tests. This can mean that your or your child’s liver is not working properly. If you or your child go into hospital or visit another doctor or a dentist, tell them you are taking Epilim.



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

4. Possible side effects

Like all medicines, Epilim can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

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- You have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called ‘erythema multiforme’
- Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called ‘Stevens-Johnson syndrome’
- Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called ‘Toxic epidermal necrolysis’
- Bruising more easily and getting more infections than usual. This could be a blood problem called ‘thrombocytopenia’. It can also be due to a fall in the number of white blood cells, bone marrow depression or another condition that affects red blood cells, white blood cells and platelets (pancytopenia) or how the blood clots
- Blood clotting problems (bleeding for longer than normal), bruising or bleeding for no reason
- Changes in mood, loss of memory, lack of concentration and deep loss of consciousness (coma)
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism)
- Breathing difficulty and pain due to inflammation of the lungs (pleural effusion)

Tell your doctor as soon as possible if you have any of the following side effects:

- Changes in behaviour including being very alert, and sometimes also aggressive, hyper-active and unusual or inappropriate behaviour. This is more likely if other medicine to treat fits such as phenobarbital and topiramate are taken at the same time or if the Epilim starting dose is high or has been suddenly increased
- Changes in the amount of ammonia in the blood. Symptoms of this condition are being sick, problems with balance and co-ordination, feeling lethargic or less alert
- Feeling shaky (tremor), sleepy or unsteady when walking or jerky muscle movements
- Feeling tired or confused with loss of consciousness sometimes accompanied by hallucinations or fits
- Blisters with the skin flaking away
- Rapid, uncontrollable movement of the eyes

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:

- Feeling sick, stomach ache or diarrhoea, especially when starting treatment. This may be helped by taking the tablets with food
- Fainting
- Hearing loss
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine
- Acne
- Hair loss which is usually temporary. When it grows back it may be more curly than before
- Hair, including body or facial hair grows more than normal in women
- Skin rash caused by narrow or blocked blood vessels (vasculitis)
- Changes in women’s periods and increased hair growth in women
- Breast enlargement in men
- Swelling of the feet and legs (oedema)
- Weight gain - as your appetite may be increased
- Kidney problems, bedwetting or increased need to pass urine
- Headache
- Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, and learning disorder
- Tingling or numbness in the hands and feet

Bone Disorders

There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.

Blood tests

Epilim can change levels of liver enzymes, salts or sugars shown up on blood and urine tests.

Male Fertility

Taking Epilim can be a contributing factor in male infertility.

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 at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Epilim

Keep out of the reach and sight of children.

Do not take this medicine after the expiry date shown on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not remove the tablets from the foil until just before you take them. Do not cut the blister strips. Store in a dry place below 30°C.

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 protect the environment.

6. Further Information

What Epilim contain

- Each 200mg gastro-resistant tablet contains 200mg of the active substance, sodium valproate
- Each 500mg gastro-resistant tablet contains 500mg of the active substance, sodium valproate
- The other ingredients are povidone (E1201), talc, calcium silicate (E552), magnesium stearate (E572), hypromellose (E464), citric acid monohydrate (E330), macrogol 6000, polyvinyl acetate phthalate, diethyl phthalate, stearic acid (E570), titanium dioxide (E171), amaranth aluminium lake (E123), indigo carmine lake (E132) and hydroxypropyl cellulose (E463)

What Epilim looks like and contents of the pack

Epilim tablets are round and lilac coloured. The tablets are supplied in blister packs of 100

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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