Package leaflet: Information for the user

Dyzantil 200mg prolonged-release tablets
Dyzantil 300mg prolonged-release tablets
Dyzantil 500mg prolonged-release tablets

sodium valproate

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

WARNING

Dyzantil, sodium valproate, can seriously harm an unborn baby when taken during pregnancy. If you are a female able to have a baby you should use an effective method of birth control (contraception) without interruption during your entire treatment with Dyzantil.

Your specialist will discuss this with you but you must also follow the advice in section 2 of this leaflet.

Schedule an urgent appointment with your general practitioner (GP) for a referral to a specialist if you want to become pregnant or if you think you are pregnant.

Do not stop taking Dyzantil unless your doctor tells you to as your condition may become worse.

If you are a parent or caregiver of a female child treated with Dyzantil, you must also read section 2 of this leaflet carefully and contact your child's GP once they experience their first period, the GP will refer your child to their specialist.

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, please ask your GP, specialist or pharmacist.
- This medicine has been prescribed for you. 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 GP, specialist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1 What Dyzantil is and what it is used for

What Dyzantil is

The name of your medicine is Dyzantil 200, 300 and 500mg prolonged-release tablets. "Prolonged-release" means that the active ingredient sodium valproate is slowly released from the tablets over a period of time.

What Dyzantil contains

Dyzantil 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 Dyzantil is used for

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

For male patients aged under 55 years not having used valproate before and for female patients aged under 55 years: this medicine is only used when two specialists have agreed that your condition does not respond to other treatments.

2 What you need to know before you take Dyzantil

Do not take Dyzantil if:

- You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of Dyzantil (listed in section 6). 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, especially if caused by taking a medicine.
- You have a rare illness called porphyria which affects your metabolism.
- You have a known metabolic disorder, i.e. a urea cycle disorder.
- You have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).
- You have a deficiency in carnitine (a very rare metabolic disease) that is untreated.
- You are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks (see 'Pregnancy, breast-feeding and fertility – Important advice for women' below).
- If you are a woman under the age of 55 years who is able to have a baby, you must not take Dyzantil unless two different specialists agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks, and you use an effective method of birth control (contraception) at all times during your entire treatment with Dyzantil. Do not stop taking Dyzantil or your contraception until you have discussed this with your specialist. Your specialist will advise you further (see below under 'Pregnancy, breast-feeding and fertility – Important advice for women').

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

Warnings and precautions

- The risk of liver damage is increased if Dyzantil is taken by children under 3 years of age, in people taking other antiepileptic medicine at the same time or having other neurological or metabolic disease and severe forms of epilepsy.
- 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 GP or specialist.
- As with other anti-epileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your GP or specialist immediately.
- If you or your child taking Dyzantil develops problems with balance and co-ordination, feeling lethargic or less alert, vomiting, tell your doctor immediately. This may be due to increased amount of ammonia in the blood.
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme and angioedema have been reported in association with valproate treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your specialist, GP or pharmacist before taking Dyzantil if:

- You have a brain disease or a metabolic condition affecting your brain.
- You have problems with your pancreas.
- You have diabetes or are being tested for diabetes. This medicine may affect the results of urine tests.
- You know or your doctor suspects that there is a genetic problem caused by a mitochondrial disorder in your family, because of a risk of damage to your liver.
- You are suspected to suffer from any metabolic disorders, particularly hereditary enzyme deficiency disorders such as a "urea cycle disorder" because of a risk of increased ammonia level in the blood.
- You have a rare disorder named 'carnitine palmitoyltransferase type II deficiency', because you are at an increased risk of muscle disorders.
- You have impaired dietary intake in carnitine, found in meat and dairy products, especially in children less than 10 years old.
- You have a deficiency in carnitine and are taking carnitine.
- You have kidney problems. Your specialist may monitor your valproate level or adjust your dose.
- You have an illness called 'systemic lupus erythematosus (SLE)' – a rare disease of the immune system which affects skin, bones, joints and internal organs.
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking valproate.

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

Weight gain

Taking Dyzantil may make you put on weight. Talk to your specialist, GP or pharmacist about how this will affect you.

Blood tests

Your GP and/or specialist may request blood tests and liver function tests before and during your treatment with this medicine. Dyzantil can change the levels of liver enzymes shown in blood tests. This can mean that your or your child's liver is not working properly.

Other medicines and Dyzantil

Tell your GP, specialist or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Dyzantil can affect the way some other medicines work. Also, some medicines can affect the way Dyzantil works.

In particular, check with your GP, specialist or pharmacist if you are taking any of the following:

- Some medicines used for pain and inflammation (salicylates) such as aspirin.
- Some other medicines used to treat fits (epilepsy) – see section 3, 'Patients taking other medicines for fits'. This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, rufinamide, topiramate, acetazolamide, lamotrigine and felbamate.
- Cannabidiol (used to treat epilepsy and other conditions).
- Medicines used to calm emotional and mental health disorders (including schizophrenia, bipolar disorder and depression) such as quetiapine, diazepam and olanzapine.
- Monoamine oxidase inhibitors (MAOIs) such as moclobemide (used to treat depression and anxiety), selegiline (used to treat Parkinson's disease), linezolid (used to treat infections).
- Anticoagulants such as warfarin – used to thin the blood and prevent clots. Your doctor may change your dose of the blood thinning medicine and monitor your treatment closely.
- Zidovudine and protease inhibitors such as lopinavir and ritonavir – used to treat HIV infection and AIDs.
- Carbapenem agents (antibiotics used to treat bacterial infections) such as panipenem, imipenem, meropenem, rifampicin and erythromycin. The combination of Dyzantil and carbapenems should be avoided because it may decrease the effect of your medicine.
- Some anti-infectives that contain pivalate (e.g., pivampicillin, adefovir dipivoxil).
- Some medicines used to treat or prevent malaria such as mefloquine and chloroquine.
- Temozolomide – used to treat cancer.
- Cimetidine – used to treat stomach ulcers.
- Cholestyramine – used to lower blood fat (cholesterol) levels.
- Nimodipine – used to treat bleeding in the brain (subarachnoid haemorrhage).
- Propofol – used for anaesthesia.
- Oestrogen – containing products (including some birth control pills).
- Metamizole – used to treat pain and fever.
- Methotrexate – used to treat cancer and inflammatory diseases.
- Clozapine – used to treat mental health conditions.

Taking Dyzantil with alcohol

Alcohol intake is not recommended during treatment.

Pregnancy, breast-feeding and fertility

Important advice for female patients under the age of 55 years

- You must not use Dyzantil if you are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks.
- If you are a female patient aged under 55 years, you must not take Dyzantil unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. If you are able to have a baby, you must use an effective method of birth control (contraception) at all times during your entire treatment with Dyzantil.
- Do not stop taking Dyzantil or your birth control (contraception), until you have discussed this with your specialist. Your specialist will advise you further.

The risks of valproate when taken during pregnancy

- Contact your GP immediately if you are planning to have a baby or are pregnant. Your GP will urgently refer you to your specialist.
- Valproate carries a risk if taken during pregnancy. The higher the dose, the higher the risks but all doses carry a risk, including when valproate is used in combination with other medicines to treat epilepsy.
- It can cause serious birth defects and can affect the physical and mental development of the child as it grows after birth and may lead to permanent disability. If you take valproate during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. Because valproate has been used for many years we know that in women who take valproate around 11 babies in every 100 will have birth defects. This compares to 2-3 babies in every 100 born to women from the general population.
  - The most frequently reported birth defects include spina bifida (where the bones of the spine are not properly developed); facial and skull malformations; heart, kidney, urinary tract and sexual organ malformations; limb defects and multiple associated malformations affecting several organs and parts of the body. Birth defects may result in disabilities which may be severe and/or permanent.
  - Hearing problems or deafness have been reported in children exposed to valproate during pregnancy.
  - Eye malformations have been reported in children exposed to valproate during pregnancy in association with other congenital malformations. These eye malformations may affect vision.
- It is estimated that up to 30-40% of children whose mothers took valproate during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, intellectually less able than other children, and have difficulty with language and memory.
  - Autism and related disorders are more often diagnosed in children exposed to valproate during pregnancy and there is some evidence children exposed to valproate during pregnancy are at increased risk of developing Attention Deficit Hyperactivity Disorder (ADHD).
- If you take valproate during pregnancy, your baby may have a lower weight than expected for their age at birth.
- Before prescribing this medicine to you, two specialists will have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks, and your specialists will have explained what might happen to your baby if you become pregnant whilst taking valproate.
- If you decide later that you want to have a baby, you must not stop taking your medicine or your method of birth control (contraception) until you have discussed this with your specialist.
- If you are a parent or a caregiver of a female child treated with valproate, you must contact their GP once your child using valproate experiences their first period (menarche). Their GP will refer your child to their specialist who will decide with another specialist whether valproate is the only possible treatment or whether another medicine should be prescribed.
- Some birth control pills (oestrogen-containing birth control pills) may lower valproate levels in your blood. Make sure you talk to your GP, specialist or sexual health and contraception clinic about the method of birth control (contraception) that is the most appropriate for you.
- Ask your specialist about taking folic acid when planning to have a baby. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However, it is unlikely that it will reduce the risk of birth defects associated with valproate use.

Please choose the situations which apply to you and read the descriptions below:

- **I AM STARTING TREATMENT WITH DYZANTIL**
- **I AM TAKING DYZANTIL AND NOT PLANNING TO HAVE A BABY**
- **I AM TAKING DYZANTIL AND PLANNING TO HAVE A BABY**
- **I AM PREGNANT AND I AM TAKING DYZANTIL**

I AM STARTING TREATMENT WITH DYZANTIL

If you are a female patient under the age of 55 years who is able to have a baby, this medicine can only be prescribed for you if two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. If this is the first time you have been prescribed Dyzantil, your specialist will have explained the risks to an unborn child if you become pregnant. If you are able to have a baby, you must use an effective method of birth control (contraception) at all times during your entire treatment with Dyzantil. Talk to your GP, specialist or sexual health and contraception clinic if you need advice on birth control (contraception).

Key messages:

- Pregnancy must be excluded before start of treatment with Dyzantil with the result of a pregnancy test, confirmed by your specialist.
- You must use an effective method of birth control (contraception) at all times during your entire treatment with Dyzantil.
- You must discuss appropriate and effective methods of birth control (contraception) with your GP or specialist. Your GP or specialist will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control (contraception).
- You must get regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your specialist will reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. The specialist will make sure you are well aware of and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your specialist if you want to have a baby.
- Tell your specialist **immediately** if you are pregnant or think you might be pregnant.

I AM TAKING DYZANTIL AND NOT PLANNING TO HAVE A BABY

If you are a female patient aged under 55 years who is able to have a baby, this medicine can only be prescribed for you if two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. If you are continuing treatment with Dyzantil and you are not planning to have a baby, you must use an effective method of birth control (contraception) at all times during your entire treatment with Dyzantil. Talk to your GP, specialist or sexual health and contraception clinic if you need advice on birth control (contraception).

Key messages:

- You must use an effective method of birth control (contraception) at all times during your entire treatment with Dyzantil.
- You must discuss appropriate and effective methods of birth control (contraception) with your GP or specialist. They will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control (contraception).
- You must get regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your specialist will reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. They will make sure you are well aware of and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your GP or specialist if you want to have a baby.
- Tell your specialist, or GP to be urgently referred to your specialist, **immediately** if you are pregnant or think you might be pregnant.

I AM TAKING DYZANTIL AND PLANNING TO HAVE A BABY

If you are planning to have a baby, first schedule an appointment with your GP. Your GP will urgently refer you to your specialist. Do not stop taking Dyzantil or your birth control (contraception) until you have discussed this with your specialist. Your specialist will advise you further.

Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development (behaviour and learning disorders), which can be seriously debilitating and/or permanent. Babies are also at risk of lower weight than expected for their age at birth. Your GP will refer you to a specialist experienced in the management of epilepsy, so that other treatment options are evaluated early on. Your specialist can put several actions in place so that your pregnancy goes as smoothly as possible and any risks to you and your unborn child are reduced as much as possible.

You must not use Dyzantil if you are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. Your specialist may decide to change the dose of Dyzantil, switch you to another medicine and stop treatment with Dyzantil a long time before you become pregnant – this is to make sure your illness is stable.

Ask your specialist about taking folic acid when planning to have a baby. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However, it is unlikely that it will reduce the risk of birth defects associated with valproate use.

Key messages:

- Do not stop taking Dyzantil unless your specialist tells you to.
- Do not stop using your birth control (contraception) before you have talked to your specialist and worked together on a plan to ensure your condition is controlled and the risks to you and your baby are reduced.
- First schedule an appointment with your specialist. During this visit your specialist will reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. They will make sure you are well aware of and have understood all the risks and advice related to the use of valproate during pregnancy.
- Your specialist will try to switch you to another medicine or stop treatment with Dyzantil a long time before you become pregnant.
- Schedule an urgent appointment with your specialist, or GP to be urgently referred to your specialist, **immediately** if you are pregnant or think you might be pregnant.

I AM PREGNANT AND I AM TAKING DYZANTIL

Do not stop taking Dyzantil unless your specialist tells you to as your condition may become worse.

Schedule an urgent appointment with your GP. Your GP will refer you immediately to your specialist if you are pregnant or think you might be pregnant. Your specialist will then advise you further.

Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development (behaviour and learning disorders) which can be seriously debilitating and/or permanent. Babies are also at risk of lower weight than expected for their age at birth. Your GP will refer you to a specialist experienced in the management of epilepsy so that other treatment options can be evaluated.

In the exceptional circumstances when two specialists have agreed that Dyzantil is the only available treatment option during pregnancy, you will be monitored very closely both for the management of your underlying condition and to check how your unborn child is developing.

You and your partner should receive counselling and support regarding the valproate exposed pregnancy.

Ask your specialist about taking folic acid. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However, it is unlikely that it will reduce the risk of birth defects associated with valproate use.

Key messages:

- Schedule an urgent appointment with your GP. Your GP will refer you immediately to your specialist, if you are pregnant or think you might be pregnant. The specialist will then advise you further.
- Do not stop taking Dyzantil unless your specialist tells you to.

- Make sure you are referred to a specialist experienced in the treatment of epilepsy to evaluate the possibility of other treatment options.
- You must get thorough counselling on the risks of Dyzantil during pregnancy, including malformations and physical and mental development disorders in children.
- Make sure you are referred to a specialist for prenatal monitoring to examine for potential malformations.

Make sure you read the Patient Guide that you will receive from your specialist, GP or pharmacist. If you are a female of childbearing potential, your specialist will discuss and complete the Annual Risk Acknowledgement Form with you and will ask you to sign it and keep it. You will also receive a Patient Card from your pharmacist to remind you of valproate risks in pregnancy.

Newborn babies of mothers who took valproate during pregnancy may have:

- Blood clotting problems (such as blood 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).
- Withdrawal syndrome (including agitation, irritability, hyperexcitability, jitteriness, hyperkinesia, muscle problems, tremor, convulsions and feeding problems). In particular, this may occur in newborns whose mothers have taken valproate during the last trimester of their pregnancy.

Breast-feeding

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

Important advice for male patients under the age of 55 years

- If you are a male aged under 55 years, before prescribing this medicine to you for the first time, two specialists will have agreed that your condition does not respond to other treatments or the risk to infertility does not apply to you.
- Your specialist will have explained to you the known risk of male infertility (see section 4 Possible side effects) and the potential risk in children born to fathers treated with valproate.
- If you are a parent or a caregiver of a male child treated with valproate, a specialist will explain to you that there are studies showing toxic effects of valproate on the testes of animals receiving the medicine and it is unclear what this means for humans.

Potential risks related to taking valproate in the 3 months before conception of a child

A study suggests a possible risk of mental and movement related developmental disorders (problems with early childhood development) in children born to fathers treated with valproate in the 3 months before conception. In this study, around 5 children in 100 had such disorders when born to fathers treated with valproate as compared to around 3 children in 100 when born to fathers treated with lamotrigine or levetiracetam (other medicines that can be used to treat your disease). Other studies did not suggest an increased risk of mental developmental disorders (problems with early childhood development) in children born to fathers treated with valproate in the 3-4 months before conception. In these studies the risk was similar compared to children of fathers treated with lamotrigine or levetiracetam before conception.

Differences in how these studies were designed may explain the different results. Overall, it is not known whether any possible risk of childhood developmental disorders is caused by valproate itself or by other factors, such as the father's underlying medical condition.

As a precautionary measure, your GP or specialist will discuss with you:

- The potential risk in children born to fathers treated with valproate.
- The need to consider effective contraception (birth control) for you and your female partner during treatment and for 3 months after stopping treatment.
- The need to consult your specialist when you are planning to conceive a child and before stopping contraception (birth control).
- The possibility of other treatments that can be used to treat your disease, depending on your individual situation.

Do not donate sperm when taking valproate or for 3 months after stopping valproate.

Talk to your GP or specialist if you are thinking about having a baby.

If your female partner becomes pregnant while you used valproate in the 3 month period before conception and you have questions, contact your GP or specialist. Do not stop your treatment without talking to your GP or specialist. If you stop your treatment, your symptoms may become worse.

You should get regular appointments with your GP. During this visit your GP will discuss with you the precautions associated with valproate use. They will refer you to a specialist to discuss the possibility of other treatments that can be used to treat your disease, depending on your individual situation.

Make sure you read the Patient Guide that you will receive from your specialist, GP or pharmacist.

If you are a male patient aged under 55 years starting treatment with valproate, your specialist will discuss and complete a risk acknowledgement form with you and will ask you to sign it and keep it.

Driving and using machines

You may feel sleepy when taking Dyzantil. 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.

Dyzantil contains sodium

Dyzantil 200 contains 18.43mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to less than 1% of the recommended maximum daily dietary intake of sodium for an adult per tablet.

Dyzantil 300 contains 27.65mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to less than 2% of the recommended maximum daily dietary intake of sodium for an adult per tablet.

Dyzantil 500 contains 46.08mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to less than 3% of the recommended maximum daily dietary intake of sodium for an adult per tablet.

3 How to take Dyzantil

Always take Dyzantil exactly as your specialist has told you. Check with your specialist, GP or pharmacist if you are not sure.

Dyzantil treatment must be started and supervised by a specialist experienced in the treatment of epilepsy.

Your specialist will decide how much Dyzantil to give you or your child depending on body weight. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your GP or specialist.

How to take this medicine

- Take this medicine by mouth. **Do not** crush or chew the tablets.
- Take Dyzantil with or after food. This will help to stop the feelings of sickness that may happen after taking Dyzantil.
- This medicine can be taken once or twice daily.
- You may see what appears to be part of the tablet in your stool. This is normal as the matrix of Dyzantil is not digested by the body. It does not mean that the medicine is not working.

How much to take:

Adults (including the elderly)

- The starting dose is 600mg daily. Your specialist should gradually increase this dose by 200mg every 3 days depending on your condition.
- The usual dose is 1000-2000mg (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 specialist should increase this dose depending on your child's illness.
- The usual dose is then 20-30mg 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

- Dyzantil is not recommended in children that weigh less than 20 kilograms. Liquid formulations of sodium valproate are recommended instead.

Patients with kidney problems

- Your specialist may decide to adjust your dose 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 Dyzantil. If so, your specialist should gradually initiate treatment depending on your or your child's condition.
- Your specialist may increase the dose of Dyzantil by 5-10mg for each kilogram of body weight each day depending on which other medicines you are taking.

If you take more Dyzantil than you should

If you or your child take more Dyzantil than you should, contact your GP or specialist urgently or go to a hospital casualty department immediately. 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, headache, blurred vision due to pupil of the eye becoming smaller, dizziness, poor reflexes, confusion, memory loss and tiredness. You may also have weak or 'floppy' muscles, fits (seizures), loss of consciousness, behavioural changes and breathing difficulties such as fast breathing, shortness of breath or chest pain.

If you forget to take Dyzantil

If you or your child 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 Dyzantil

Do not stop taking Dyzantil or alter your or your child's dose without checking with your specialist. If you or your child stop taking Dyzantil without your specialist's advice, your condition may get worse.

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

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

4 Possible side effects

Like all medicines, Dyzantil can cause side effects, although not everybody gets them. Side effects are more likely to happen at the start of treatment.

Tell your GP, specialist or go to a hospital straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- You have an **allergic reaction** which may manifest as:
  - Blisters with skin detachment (blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without rash), sometimes with flu-like symptoms such as fever, chills, or aching muscles. These may be signs of conditions named 'Toxic epidermal necrolysis' or 'Stevens-Johnson Syndrome'.
  - 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 may be signs of a condition named 'erythema multiforme'.
  - Allergy-triggered swelling with painful itchy welts (most often around the eyes, lips, throat and sometimes hands and feet) and swallowing or breathing problems. These may be signs of 'angioedema' or an anaphylactic reaction.
  - Syndrome with skin rash, fever, lymph node enlargement and possible impairment of other organs. These may be signs of a condition named 'Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)'.
- 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 Dyzantil. It includes feeling sick (nauseas) and being sick (vomiting) many times; extreme tiredness, drowsiness and weakness; stomach pain including severe upper stomach pain; yellowing of the skin or whites of the eyes (jaundice); loss of appetite; swelling of the legs and feet (may also 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 Dyzantil immediately if you have these symptoms.
- Blood disorders that can be shown in blood tests. Signs may include:
  - Spontaneous bruising or bleeding due to blood clotting problems or decreased platelet count, or getting more infections than usual (thrombocytopenia).
  - Severe decrease of white blood cells or bone marrow failure, sometimes revealed by fever and breathing difficulty (agranulocytosis).
  - Decreased red blood cell count (anaemia) or abnormally increased red blood cell size (macrocytosis).
  - Bone marrow disorders that affect red blood cells, white blood cells and platelets (pancytopenia).
- Drowsiness, change in consciousness level (including coma), confusion, loss of memory, abnormal behaviour including changes in attention, concentration and mood. This could also be associated with hallucinations or more frequent or severe fits. This is more likely if other medicine to treat fits such as phenobarbital and topiramate are taken at the same time or if the Dyzantil starting dose is high or has been suddenly increased.
- Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism).
- Difficulty breathing, pain or pressure in the chest (especially when breathing in), shortness of breath and dry cough due to buildup of fluid around the lungs (pleural effusion).
- An increase in the number and severity of convulsions.
- Muscle pain and weakness (rhabdomyolysis).
- Joint pain, fever, fatigue or rash. These may be signs of systemic lupus erythematosus (SLE).
- Problems with balance and co-ordination, feeling lethargic or less alert, associated with being sick (vomiting). This may be due to an increased amount of ammonia in your blood.
- Shakiness (tremor), jerky muscle movements, unsteadiness when walking (parkinsonism, extrapyramidal disorder, ataxia).
- Rapid, uncontrollable movement of the eyes.
- Kidney disease or kidney problems (renal failure, tubulointerstitial nephritis and Fanconi syndrome) which may manifest as reduced urinary output or blood in the urine.
- Confusion, that could be due to decreased levels of sodium in your blood, identified by a blood test, or to a condition named 'Syndrome of Inappropriate Antidiuretic Hormone (SIADH) secretion'.

Tell your GP, specialist 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 (nausea), being sick (vomiting), stomach ache or diarrhoea, especially when starting treatment. This may be helped by taking the tablets with food.
- Overgrowth of gums (gingival hypertrophia), swelling of gums or mouth, sore mouth, mouth ulcers and burning feeling of mouth (stomatitis).
- Headache.
- Hearing loss, hearing problems or deafness.
- Double vision.
- Nail and nail bed disorders.
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine.
- Transient hair loss, abnormal hair growth, abnormal hair texture, changes in hair colour.
- Darker areas of skin and mucosae (hyperpigmentation).
- Increased levels of some hormones (androgens), which may lead to increased hair growth on the face, breasts or chest (particularly in women), acne or thinning hair.
- Skin rash caused by inflammation of small blood vessels (vasculitis).
- Irregularity or absence of women's period, pain during women's period, cysts in the ovaries (polycystic ovaries).
- Breast enlargement in men, male infertility (usually reversible after treatment discontinuation and may be reversible after dose reduction. Do not stop your treatment without speaking to your specialist first).
- Swelling of the feet and legs (oedema).
- Obesity, weight gain – as your appetite may be increased.
- Bedwetting or increased need to pass urine, urinary incontinence (unintentional passing of urine).
- Passing a lot of urine and feeling thirsty (Fanconi syndrome).
- Decrease in carnitine levels (shown in blood or muscular tests).
- Seeing, feeling or hearing things that are not there (hallucinations).
- Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, memory impairment, or cognitive or learning disorder.
- Tingling or numbness in the hands and feet.
- Lowering of normal body temperature.

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

Tests

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

Additional side effects in children

Some side effects of valproate occur more frequently in children or are more severe compared to adults. These include liver damage, inflammation of the pancreas (pancreatitis), bedwetting (enuresis), renal dysfunction (Fanconi Syndrome), overgrowth of gum tissue, aggression, agitation, disturbance in attention, abnormal behaviour, hyperactivity and learning disorder.

Reporting of side effects

If you get any side effects, talk to your GP, specialist, 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 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 Dyzantil

Keep out of the sight and reach 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. These measures help protect the tablets from moisture and light.

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 Contents of the pack and other information

What Dyzantil contains

- Each 200mg prolonged-release tablet contains a mixture of 133.2mg sodium valproate and 58mg valproic acid, equivalent to 200mg of the active substance sodium valproate.
- Each 300mg prolonged-release tablet contains a mixture of 199.8mg sodium valproate and 87mg valproic acid, equivalent to 300mg of the active substance sodium valproate.
- Each 500mg prolonged-release tablet contains a mixture of 333mg sodium valproate and 145mg valproic acid, equivalent to 500mg of the active substance sodium valproate.

The other ingredients are:

- For Dyzantil 200mg and 500mg prolonged-release tablets: hypromellose (E464), ethylcellulose, hydrated silica, titanium dioxide (E171), erythrosine aluminium lake (E127), indigo carmine aluminium lake (E132), iron oxide black (E172), macrogol 400.
- For Dyzantil 300mg prolonged-release tablets: hypromellose (E464), ethylcellulose, hydrated silica, titanium dioxide (E171), indigo carmine aluminium lake (E132), iron oxide black (E172), macrogol 400.

What Dyzantil looks like and contents of the pack

- Dyzantil 200mg and 500mg prolonged-release tablets: Violet coloured, oblong shaped, prolonged-release tablets, plain on both sides.
- Dyzantil 300mg prolonged-release tablets: Blue coloured, oblong shaped, prolonged-release tablets, plain on both sides.

Pack sizes:

14, 30, 48, 72, 90, 100 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Aspire Pharma Ltd
Unit 4, Rotherbrook Court, Bedford Road
Petersfield, Hampshire, GU32 3QG, 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 GP, specialist or pharmacist.

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Other sources of information

This leaflet is available in alternative formats such as audio, CD-ROM or large print. Please contact Aspire Pharma Ltd via telephone: (+44) 01730 231148 or email: medinfo@aspirepharma.co.uk for more information.

qr.valproateandme.co.uk

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