

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

Schedule an urgent appointment with your doctor 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 doctor once they experience their first period.

**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 further questions, please 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 symptoms 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 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.

## 2 What you need to know before you take Dyzantil

### Do not take Dyzantil and tell your doctor 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.
- You have a rare illness called porphyria.
- 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 are pregnant, unless nothing else works for you (see 'Pregnancy, breast-feeding and fertility – Important advice for women' below).

If you are a woman able to have a baby you must not take Dyzantil unless you use an effective method of birth control (contraception) at all times during your treatment with Dyzantil. Do not stop taking Dyzantil or your contraception until you have discussed this with your doctor. Your doctor 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 doctor or pharmacist before taking Dyzantil.

### Warnings and precautions

- 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.
  - As with other anti-epileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your doctor immediately.
  - Talk to your doctor or pharmacist before taking Dyzantil if:
    - You have diabetes. This medicine may affect the results of urine tests.
    - You have a carnitine palmitoyltransferase type II deficiency.
    - You have kidney problems. Your doctor may give you a lower dose.
    - You have a 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.
    - You know that there is a genetic problem caused by a mitochondrial disorder in your family.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Dyzantil.

### Weight gain

Taking Dyzantil 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 Dyzantil and during your treatment.

### Other medicines and Dyzantil

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 Dyzantil can affect the way some other medicines work. Also some medicines can affect the way Dyzantil works.

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

- 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.

### Dyzantil 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 health problems (including schizophrenia, bipolar disorder and depression) such as quetiapine, diazepam and olanzapine.
- Nimodipine.
- Propofol – used for anaesthesia.

### The following medicines can affect the way Dyzantil works:

- Oestrogen-containing products (including some birth control pills).
- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine.
- Cimetidine used for stomach ulcers.
- Protease inhibitors such as lopinavir and ritonavir – used for HIV infection and AIDS.
- Carbapenem antibiotics (antibiotics used to treat bacterial infections) such as imipenem, meropenem, rifampicin and erythromycin. The combination of Dyzantil and carbapenems should be avoided because it may decrease the effect of your medicine.
- Cholestyramine used to lower blood fat (cholesterol) levels.

### Taking Dyzantil with food and drink

Alcohol intake is not recommended during treatment.

## Pregnancy, breast-feeding and fertility

### Important advice for women

- You must not use Dyzantil if you are pregnant, unless nothing else works for you.
- If you are a woman able to have a baby, you must not take Dyzantil unless you use an effective method of birth control (contraception) during your entire treatment with Dyzantil.
- Do not stop taking Dyzantil or your birth control (contraception), until you have discussed this with your doctor. Your doctor will advise you further.

### The risks of valproate when taken during pregnancy

- Talk to your doctor immediately if you are planning to have a baby or are pregnant.
- Valproate carries a risk if taken during pregnancy. The higher the dose, the higher the risks but all doses carry a risk.
- It can cause serious birth defects and can affect the way in which the child develops as it grows. Birth defects which have been reported 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.
- 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 10 babies in every 100 will have birth defects. This compares to 2-3 babies in every 100 born to women who don't have epilepsy.
- It is estimated that up to 30-40% of preschool 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.
- Autistic spectrum disorders are more often diagnosed in children exposed to valproate and there is some evidence children may be more likely to develop symptoms of Attention Deficit Hyperactivity Disorder (ADHD).
- Before prescribing this medicine to you, your doctor will have explained what might happen to your baby if you become pregnant whilst taking valproate. If you decide later you want to have a child you should not stop taking your medicine or your method of birth control (contraception) until you have discussed this with your doctor.
- If you are a parent or a caregiver of a female child treated with valproate, you should contact their doctor once your child experiences their first period (menarche).
- Some birth control pills (oestrogen-containing birth control pills) may lower valproate levels in your blood. Make sure you talk to your doctor about the method of birth control (contraception) that is the most appropriate for you.
- Ask your doctor about taking folic acid when trying for 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 this is the first time you have been prescribed Dyzantil your doctor will have explained the risks to an unborn child if you become pregnant. Once you are able to have a baby, you will need to make sure you use an effective method of birth control (contraception) without interruption throughout your treatment with Dyzantil. Talk to your doctor or family planning 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 doctor.
- You must use an effective method of birth control (contraception) during your entire treatment with Dyzantil.
- You must discuss appropriate methods of birth control (contraception) with your doctor. Your doctor 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 doctor 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 doctor if you want to have a baby.
- Tell your doctor **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 continuing treatment with Dyzantil but you are not planning to have a baby, make sure you are using an effective method of birth control (contraception) without interruption during your entire treatment with Dyzantil. Talk to your doctor or family planning clinic if you need advice on birth control (contraception).

### Key messages:

- You must use an effective method of birth control (contraception) during your entire treatment with Dyzantil.
- You must discuss birth control (contraception) with your doctor. Your doctor 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 doctor 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 doctor if you want to have a baby.
- Tell your doctor **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 doctor.

Do not stop taking Dyzantil or your birth control (contraception) until you have discussed this with your doctor. Your doctor will advise you further.

Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development, which can be seriously debilitating. Your doctor will refer you to a specialist experienced in the management of epilepsy, so that alternative treatment options can be 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.

Your specialist may decide to change the dose of Dyzantil, switch you to another medicine, or stop treatment with Dyzantil a long time before you become pregnant – this is to make sure your illness is stable.

Ask your doctor about taking folic acid when trying for 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 doctor tells you to.
- Do not stop using your birth control (contraception) before you have talked to your doctor and worked together on a plan to ensure your condition is controlled and the risks to your baby are reduced.
- First schedule an appointment with your doctor. During this visit your doctor 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 doctor 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 doctor if you are pregnant or think you might be pregnant.

### I AM PREGNANT AND I AM USING DYZANTIL

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

Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant. Your doctor will advise you further.

Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development which can be seriously debilitating. You will be referred to a specialist experienced in the management of epilepsy so that alternative treatment options can be evaluated.



In the exceptional circumstances when Dyazantil 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 doctor 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 doctor if you are pregnant or think you might be pregnant.
- Do not stop taking Dyazantil unless your doctor tells you to.
- Make sure you are referred to a specialist experienced in the treatment of epilepsy to evaluate the need for alternative treatment options.
- You must get thorough counselling on the risks of Dyazantil during pregnancy, including malformations and developmental effects in children.
- Make sure you are referred to a specialist for prenatal monitoring in order to detect possible occurrences of malformations.

**Make sure you read the Patient Guide that you will receive from your doctor. Your doctor will discuss the Annual Risk Acknowledgement Form 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 Dyazantil 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 Dyazantil. 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 Dyazantil

Always take Dyazantil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Dyazantil treatment must be started and supervised by a doctor specialised in the treatment of epilepsy.

#### Taking this medicine

- Your doctor will decide how much Dyazantil to give you or your child depending on your or your child's body weight.
- Take this medicine by mouth.
- Take Dyazantil with or after food. This will help to stop the feelings of sickness that may happen after taking Dyazantil.
- **Do not** crush or chew the tablets. Swallow whole with a glass of water.
- 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

- This medicine can be taken once or twice daily.

#### How much to take

##### Adults (including the elderly)

- The starting dose is 600mg daily. Your doctor will gradually increase this dose by 200mg every 3 days depending on your condition.
- The usual dose is generally 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

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

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

##### If you take more Dyazantil than you should

If you take more Dyazantil 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 Dyazantil

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 Dyazantil

Keep taking Dyazantil until your doctor tells you to stop. Do not stop taking Dyazantil 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. Dyazantil 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 Dyazantil.

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

### 4 Possible side effects

Like all medicines, Dyazantil 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 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 Dyazantil. 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 Dyazantil 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, hyperactive and unusual or inappropriate behaviour. This is more likely if other medicines to treat fits such as phenobarbital and topiramate are taken at the same time or if the Dyazantil 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.
- An increase in the number and severity of convulsions.

**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 (nausea), being sick (vomiting), stomach ache or diarrhoea, especially when starting treatment. This may be helped by taking the tablets with food.
- Swelling of gums or sore mouth.
- Fainting.
- Hearing loss.
- Nail and nail bed disorders.
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine.
- Hair disorders (changes in texture, colour or growth), hair loss which is usually temporary. When it grows back it may be more curly than before.
- Increased levels of some hormones (androgens), which may lead to increased hair growth on the face, breasts or chest, acne or thinning hair.
- 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).
- Obesity, weight gain – as your appetite may be increased.
- Kidney disease, kidney problems, blood in the urine, bedwetting or increased need to pass urine, urinary incontinence (unintentional passing of urine).
- Headache.
- Seeing or hearing things that are not there (hallucinations).
- Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, and learning disorder.
- Tingling or numbness in the hands and feet.
- Lowering of normal body temperature.
- Abnormal blood clotting factors.
- Muscle pain and weakness (rhabdomyolysis).

#### 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.

#### 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 anti-epileptic medication, have a history of osteoporosis, or take steroids.

#### Tests

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

#### Male fertility

Taking Dyazantil 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](http://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 Dyazantil

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 Dyazantil 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 Dyazantil 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 Dyazantil 300mg prolonged-release tablets: hypromellose (E464), ethylcellulose, hydrated silica, titanium dioxide (E171), indigo carmine aluminium lake (E132), iron oxide black (E172), macrogol 400.

#### What Dyazantil looks like and contents of the pack

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

This leaflet was last revised in **October 2020**.

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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](mailto:medinfo@aspirepharma.co.uk)

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