

**PATIENT INFORMATION LEAFLET**

**Sodium valproate 200mg  
and 500mg gastro-resistant  
tablets**

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.

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

**1. What sodium valproate is and what it is used for**

The name of your medicine is Sodium Valproate 200mg or 500mg Gastro-resistant Tablets (called sodium valproate throughout this leaflet). This

belongs to a group of medicines called anti-convulsants or anti-epileptic agents. It works by controlling the activity of the brain which causes fits or seizures.

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

**2. What you need to know before you take sodium valproate**

**Do not take sodium valproate and tell your doctor if:**

- You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of this medicine (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 a family history of liver problems
- 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)

**Talk to your doctor or pharmacist before taking sodium valproate 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 – you may need a lower dose
- You have a ‘urea cycle disorder’ – where too much ammonia builds up in the body
- You have an illness called “lupus” – a disease of the

immune system which affects the skin, bones, joints, lungs and kidneys

- You know that there is a genetic problem caused by a mitochondrial disorder in your family Talk to your doctor or pharmacist before taking sodium valproate if you have these conditions. Do this even if you no longer have them, but have had them in the past.

Sodium valproate can increase your appetite and may make you put on weight. Talk to your doctor about how this will affect you.

Your doctor may wish to do blood tests before you start taking sodium valproate and during the first six months of treatment.

#### **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 antiepileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your doctor immediately.

#### **Other medicines and sodium valproate**

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

In particular, check with your doctor or pharmacist if you are taking any of the

following medicines:

- Anti-psychotic agents such as quetiapine and olanzapine – for mental health problems. Sodium valproate may increase the effects of these drugs. In particular, when taken with the medicine olanzapine the following effects occur: neutropenia (a blood problem which reduces the chance of fighting infection), tremor, dry mouth, increased appetite and weight gain, problems with speech, sleepiness or extreme tiredness.
- Medicines for depression – including monoamine oxidase inhibitors (MAOI) such as moclobemide.
- Benzodiazepines (such as Diazepam) – used as sleeping tablets and for anxiety.
- Some medicines for epilepsy such as phenytoin, carbamazepine, rufinamide, topiramate, acetazolamide, phenobarbital, lamotrigine, primidone, felbamate.
- Medicines for thinning the blood such as warfarin.
- Salicylates such as aspirin
- Cholestyramine – for high blood lipid (fat) levels.
- Cimetidine - for stomach ulcers.
- Carbapenem agents (antibiotics used to treat bacterial infections) such as imipenem, meropenem, rifampicin and erythromycin. The combination of sodium valproate and carbapenems should be avoided because it may decrease the effect of your medicine.
- Mefloquine and chloroquine – used to prevent and treat malaria. Taking these with sodium valproate may increase the chance of a fit. Before travelling to a malaria area, ask your doctor or pharmacist about the best malaria prevention tablets for you.
- Zidovudine and protease inhibitors such

as lopinavir and ritonavir – for HIV and AIDS.

- Temozolomide – for cancer.
- Nimodipine.
- Propofol – used for anaesthesia.

### **Taking sodium valproate with food and drink**

Take sodium valproate with or after food. This will help to stop the feelings of sickness that may happen after taking the tablets.

Alcohol intake is not recommended during treatment.

Pregnancy, breast feeding and fertility  
Important advice for women

- Valproate can be harmful to unborn children when taken by a woman during pregnancy.
- Whether taken on its own or with another epilepsy medicine, valproate seems to carry a higher risk if taken during pregnancy than other epilepsy medicines. 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).
- If you are a woman capable of becoming pregnant your doctor should only prescribe valproate for you if nothing else works for you.
- 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 until you have discussed this with your doctor and agreed a plan for switching you onto another product if this is possible.
- 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.

### **FIRST PRESCRIPTION**

If this is the first time you have been prescribed valproate your doctor will have explained the risks to an unborn child if you become pregnant. Once you are of childbearing age, you will need to make sure you use an effective method of contraception throughout your treatment. Talk to your doctor or family planning clinic if you need advice on contraception.

#### **Key messages:**

- Make sure you are using an effective method of contraception.
- Tell your doctor at once if you are pregnant or think you might be pregnant.

### **CONTINUING TREATMENT AND NOT TRYING FOR A BABY**

If you are continuing treatment with valproate but you don't plan to have a baby make sure you are using an effective method of contraception. Talk to your doctor or family planning clinic if you need advice on contraception.

**Key messages:**

- Make sure you are using an effective method of contraception
- Tell your doctor at once if you are pregnant or think you might be pregnant.

**CONTINUING TREATMENT AND CONSIDERING TRYING FOR A BABY**

If you are continuing treatment with valproate and you are now thinking of trying for a baby you must not stop taking either your valproate or your contraceptive medicine until you have discussed this with your prescriber. You should talk to your doctor well before you become pregnant so that you 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 doctor may decide to change the dose of valproate or switch you to another medicine before you start trying for a baby.

If you do become pregnant you will be monitored very closely both for the management of your underlying condition and to check how your unborn child is developing.

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 using your contraception before you have talked to your doctor and worked

together on a plan to ensure your epilepsy is controlled and the risks to your baby are reduced.

- Tell your doctor at once when you know or think you might be pregnant.

**UNPLANNED PREGNANCY WHILST CONTINUING TREATMENT**

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. If you are taking valproate and you think you are pregnant or might be pregnant contact your doctor at once. Do not stop taking your medicine until your doctor tells you to.

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:**

- Tell your doctor at once if you know you are pregnant or think you might be pregnant.
- Do not stop taking valproate unless your doctor tells you to.

**Make sure you read the patient booklet and sign the Acknowledgement of Risk form which should be given to you and discussed with you by your doctor or pharmacist.**

**Breast-feeding**

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

**Driving and using machines**

You may feel sleepy:

- When you first start taking sodium valproate.
- If you are taking it with other

medicines, such as other antiepileptic drugs or benzodiazepines. If this happens to you, do not drive or use any tools or machines.

**Important information about some the ingredients of sodium valproate tablets**

These tablets contain:

- The colouring agent amaranth lake, which may cause an allergic reaction in some people.
- 27.6mg sodium per 200mg dose and 69mg sodium per 500mg dose. To be taken into consideration by patients on a controlled sodium diet.

**3. How to take sodium valproate**

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

Sodium valproate treatment must be started and supervised by a doctor specialised in the treatment of epilepsy.

**Taking this medicine**

- Swallow the tablets whole with a drink of water
- Do not crush or chew
- Take with or just after a meal. This will help reduce the chances of getting certain side effects such as nausea or upset stomach.

**How much to take Adults**

- The usual dose of sodium valproate is between 1000mg and 2000mg each day.
- This may be increased to 2500mg each day.
- Take this in 2 separate doses – half in the morning and half in the evening.

**Children over 20kg:**

- The dose of sodium valproate is based on the child's weight.
- The usual dose is between 20 and 30mg for each kg of body weight.
- This may be increased to 35mg for each kg of body weight each day.
- Take this in 2 separate doses – half in the morning and half in the evening.

**Children under 20kg:**

- The usual dose of sodium valproate is based on the child's weight.
- The usual dose is 20mg for each kg of body weight.
- Give in 2 separate doses – half in the morning and half in the evening.

**People with kidney problems**

If you or your child have kidney problems, your doctor may prescribe a lower dose.

Do not change the dose you have been prescribed without first discussing with your doctor.

**When treatment is first started**

At first you may be prescribed a lower dose. This is because some patients need less sodium valproate than others to control their fits. Your doctor will then increase the dosage until your condition is controlled.

- Because of this it is very important that you follow your doctor's instructions about how much to take.
- Blood tests may be needed to check how well the medicine is working.
- You may be taking other medicines for epilepsy at the same time as sodium valproate. If so, your doctor may increase the dose of sodium valproate by 5-10mg for each kg of body weight each day.

**Appointments**

Make sure you keep your regular



appointments for a check-up. They are very important as your dose may need to be changed. If you go into hospital or visit another doctor or a dentist, tell them you are taking sodium valproate.

**If you take more sodium valproate than you should**

An overdose of this medicine may be dangerous. If you think you may have taken more sodium valproate tablets than you should (or someone else has taken some), talk to a doctor, pharmacist or go to the nearest hospital casualty department straight away. Take the carton and any sodium valproate tablets left with you so that the doctors know 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 sodium valproate**

If you forget to take a dose at the right time, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before. Do not take a double dose to make up for a forgotten dose.

**If you stop taking sodium valproate**

Do not stop taking sodium valproate without first discussing this with your doctor, even if you feel better. This is because stopping suddenly may lead to your fits coming back.

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

**4. Possible side effects**

Like all medicines, sodium

valproate can cause side effects, although not everybody gets them. Usually they are not serious, and may stop if you change to another medicine.

**Stop taking sodium valproate and see a doctor or go to a hospital straight away if:**

- You get swelling of the face, lips or throat which may cause difficulty in swallowing or breathing. Hands, feet or genitals may also be affected. More severe allergic reactions can lead to lymph node enlargement and possible impairment of other organs. You could also notice an itchy, lumpy rash (hives) nettle rash (urticaria), joint pain or fever (systemic lupus erythematosus). This may mean you are having an **allergic reaction** to sodium valproate

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

- Liver problems and problems of the pancreas may show as a sudden illness which may happen in the first six months of treatment. This is a common side effect in people taking sodium valproate. 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), leg swelling, worsening of your epilepsy or a general feeling of being unwell. Your doctor may tell you to stop taking sodium valproate if you have these symptoms.

**Uncommon side effects (may affect up to 1 in 100 people)**

- Breathing difficulty and pain due to inflammation of lungs (pleural effusion)
- An increase in the number and severity of convulsions

**Rare side effects (may affect up to 1 in**

**1,000 people)**

- 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 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 (pantocytopenia)
- Blood problems such as blood clotting problems (bleeding for longer than normal), bruising or bleeding for no reason or getting infections more easily than usual. These blood problems could include bone marrow depression or how the blood clots.
- 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)

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

- Very unusual behaviour including being very alert, and sometimes also aggressive, hyper-active and showing bad behaviour. This can be associated with more frequent or severe fits, and loss of drive. This is more likely if phenobarbital and topiramate is taken at the same time or if the sodium valproate dose has been suddenly increased.
- Sleepy or unsteady when walking or jerky muscle movements. This is a common side effect (may affect up to 1 in 10 people)
- Feeling tired, confused, with loss of consciousness (coma) sometimes accompanied by hallucinations or fits. This is a common side effect (may affect up to 1 in 10 people)
- Rapid, uncontrollable movement of the eyes. This is a common side effect (may affect up to 1 in 10 people)
- Blisters with the skin flaking away. This is a rare side effect (may affect up to 1 in 10,000 people)
- 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. This is a rare side effect (may affect up to 1 in 10,000 people)

**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:**

**Very common side effects (may affect more than 1 in 10 people)**

- Feeling sick (nausea) especially when starting treatment. Feeling sick may be made better by taking the tablet with or after food.

- Feeling shaky (tremor)

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

- Being sick (vomiting), stomach ache or diarrhoea, especially when starting treatment.
- Swelling of gums or sore mouth
- Hearing problems
- Nail and nail bed disorders
- Loss of hair which is usually temporary. When it grows back it may be more curly than before
- Weight gain – as your appetite may be increased
- Headache
- Seeing or hearing things that are not there (hallucinations)
- Aggression, agitation and disturbance in attention
- Painful periods

**Uncommon side effects (may affect up to 1 in 100 people)**

- Feeling tired, confused, having hallucinations or changes in mood and loss of consciousness (coma)
- Inflamed blood vessels (vasculitis) – you may notice pain, redness or itching
- Changes in women's periods absence of periods
- Swelling of the feet and legs (oedema)
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis.
- Tingling or numbness in the hands and feet
- Hair disorders (changes in texture, colour or growth)
- Increased levels of some hormones (androgens), which may lead to increased hair growth on the face, breasts or chest, acne or thinning hair.
- Kidney disease
- Lowering of normal body temperature

**Rare side effects (may affect up to 1 in 1,000 people)**

- Abnormal blood clotting factors
- Abnormal behaviour, restlessness/hyperactivity and learning disorder
- Kidney problems, bedwetting or increased need to pass urine
- Blood in the urine
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine
- Muscle pain and weakness (rhabdomyolysis)
- Male infertility, polycystic ovaries
- Obesity

**Very rare side effects (may affect up to 1 in 10,000 people)**

- Increased breast growth in men

**Frequency unknown (cannot be estimated from available data)**

- Fainting

These effects usually get better when you stop taking sodium valproate.

**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.

Sodium valproate may decrease blood sodium. This can make you feel tired, weak, dizzy or faint. You may also feel or be sick and have muscle cramps.

Less commonly you may be bloated with swelling and tightness of the hands and feet, feel confused and have fits. Sometimes it can cause changes in the blood. Here you may notice unusual bleeding or bruising more easily, severe stomach pains, feeling shaky or



problems with balance.

#### **Male fertility**

Taking sodium valproate 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.

#### **5. How to store sodium valproate**

- Keep out of the sight and reach of children.
- Do not take this medicine after the expiry date shown on the pack.
- Store this medicine below 30°C and in a dry place.
- Store this medicine in the original container. It is important to keep sodium valproate tablets in their foil pack until you are ready to take them or they may spoil.
- Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help to protect the environment.

#### **6. Contents of the pack and other information**

##### **What Sodium Valproate Tablets contain**

Each tablet contains 200mg or 500mg of sodium valproate as the active substance.

The other ingredients are: Povidone, talc, magnesium stearate, calcium silicate, polyvinyl acetate phthalate, citric acid, hypromellose, macrogol 6000, diethyl phthalate, stearic acid, titanium dioxide, amaranth lake, indigo carmine lake and hydroxypropyl cellulose.

##### **What Sodium Valproate Tablets look like and contents of the pack**

Sodium Valproate 200mg and 500mg Tablets are round, lilac gastro-resistant tablets. They are available in blister packs of 100 tablets.

#### **7. Manufactured By:**

##### **Taj Pharmaceuticals Ltd.**

at: Plot. No. 220, Mahagujarat Industrial Estate, At & Post-Moraiya, Tal-Sanand, Dist- Ahmedabad Gujarat (India)