PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

Sodium Valproate / Valproic Acid 500

Controlled Release Tablets

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Sodium Valproate / Valproic Acid 500

Controlled Release Tablets

Package leaflet: Information for the patient

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

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist or nurse.

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

1. NAME OF THE MEDICINAL PRODUCT
Sodium Valproate / Valproic Acid 500 MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:
Sodium Valproate 333 mg/tab
Valproic Acid 145 mg/tab
corresponding to 500 mg of sodium valproate.

3. PHARMACEUTICAL FORM
Prolonged Release Tablets

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications:
Epilepsy:
Treatment of generalized or partial epilepsy, particularly with the following patterns of
seizures:
-- absence
-- myoclonic
-- tonic-clonic
-- atonic
-- mixed
as well as, for partial epilepsy:
-- simple or complex seizures
-- secondary generalized seizures
-- specific syndromes (West, Lennox-Gastaut)
Bipolar disorders:
Treatment and/or prevention of acute manic episodes in the context of bipolar disorders.
4.2 Posology and method of administration:
SODIUM VALPROATE 500 MG is a prolonged-release formulation of Depalept which reduces peak plasma 2 concentrations and ensures more regular plasma levels over a **24-hour period.**
This dosage strength of the medicinal product is reserved for use in adults and children
weighing more than 17 kg.
This dosage form is not appropriate for use in children under the age of 6 years (risk of false
passage). **Posology**
The initial daily dosage is usually 10-15 mg/kg, then doses are titrated up to the optimum
dosage. This is generally within the range of 20-30 mg/kg. Nevertheless, where seizure control is not
achieved within this range, the dose may be further increased; patients should be carefully
monitored when receiving daily doses higher than 50 mg/kg (see section 4.4 Special warnings
and special precautions for use). In children, the usual dosage is about 30 mg/kg per day. In adults, the usual dosage is within the range of 20-30 mg/kg per day. In elderly, although the pharmacokinetics of SODIUM VALPROATE 500 MG is modified, it has limited clinical significance and dosage should be determined by seizure control.
The daily dosage should be established according to age and body weight; however, the significant variations in inter-individual sensitivity to valproate should be taken into account. No clear correlation between the daily dose, serum levels and the therapeutic effect has been established: the dosage will mainly be determined on the basis of the clinical response. Determination of valproic acid plasma levels should be considered along with clinical monitoring when control of seizures is not achieved or when adverse effects are suspected. The effective therapeutic range is usually between 40 and 100 mg/L (300 to 700 µmol/L).
Method of administration
Oral use.
The daily dose should be administered in 1 dose or 2 divided doses, preferably during
meals. The use of prolonged release form (SODIUM VALPROATE 500 MG) allows to give the drug once daily in the event of well-controlled epilepsy.
SODIUM VALPROATE 500 MG may be used in children provided that they are able to take such a form.
The breakable form of SODIUM VALPROATE 500 MG allows a fine dose adjustment.
Because of the dosage and size of the tablets, SODIUM VALPROATE 500 MG should only be given
to adults and children weighing more than 17 kg. Mean dosage per 24 hours, to be given in
one or two doses: 20 to 30 mg/kg.
Administration as a single dose is possible in controlled epilepsy with one daily dose of about
20 to 30 mg/kg.
Initiation of Depalept therapy (oral administration):
-- In patients whom appropriate control has been obtained with immediate-release forms of
Depalept, it is recommended that the daily dose be maintained when replacing treatment
with SODIUM VALPROATE 500 MG.
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-- If the patient is already being treated and is taking other antiepileptics, begin administering
SODIUM VALPROATE 500 MG gradually, to reach the optimal dose in approximately two weeks, then
reduce the concomitant treatments if necessary on the basis of treatment efficacy.
-- If the patient is not taking any other antiepileptics, the dosage should preferably be increased
step-wise every 2 or 3 days, in order to reach the optimal dose in approximately one
week.
-- If necessary, combination treatment with other antiepileptics should be instituted gradually (see
section 4.5 Interaction with other medicinal products and other forms of interaction).
Treatment and prevention of manic episodes in the context of bipolar disorders:
The recommended initial dose is 1000 mg/day. The dose should be increased as fast as
possible to the lowest dose that brings about the desired clinical effect. The recommended maintenance dose for the treatment of bipolar disorders is between 1000 mg and 2000 mg
daily. In exceptional cases the dose may be increased to a maximum of 3000 mg daily. Dosage
should be adjusted individually on the basis of clinical response.
Preventive treatment of mania should be adjusted for the individual patient using the lowest effective dose.
4.3 Contraindications
-- History of hypersensitivity to valproate, divalproate, valpromide or to one of the ingredients
of the medicinal product.
-- Acute hepatitis
-- Chronic hepatitis
-- Personal or familial history of severe hepatitis, in particular drug-related.
-- Hepatic porphyria
-- Combination use with mefloquine and St. John's wort (see section 4.5 Interactions with
other medicinal products and other forms of interaction)
Generally, this medication is not recommended in combination use with lamotrigine.
4.4 Special warnings and special precautions for use
Special warnings
The introduction of an antiepileptic may, in rare cases, be followed by an increase in seizures
or the onset of a new type of seizure in the patient, independently of the spontaneous
fluctuations observed in some types of epilepsy. In the case of valproate, this mainly involves
a change in concomitant antiepileptic treatment or a pharmacokinetic interaction (see section
4.5 Interaction with other medicinal products and other forms of interaction), toxicity (liver
disease or encephalopathy) (see sections 4.4 Special warnings and special precautions for use
and 4.8 Undesirable effects) or overdose.
Since this medicinal product is transformed into valproic acid in the body, it should not be
combined with other medicinal products undergoing the same type of transformation in order
to prevent any overdose of valproic acid (for example: divalproate, valpromide).
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Liver diseases:
• Conditions of onset
Exceptional cases of liver damage with a severe or sometimes fatal outcome have been
reported.
Infants and young children under the age of 3 presenting with severe epilepsy and, in
particular, epilepsy associated with brain damage, mental retardation and/or a genetic
metabolic or degenerative disease are the most at risk. Over the age of 3, the incidence of
onset is significantly reduced and gradually decreases with age.
In the great majority of cases, such liver damage has been observed within the first 6 months
of treatment, usually between the 2nd and 12th week and generally during multiple-agent
antiepileptic treatment.
• Warning signs
Early diagnosis is primarily based on the clinical picture. In particular, two types of signs
that can precede jaundice should be taken into account, particularly in patients at risk (see
Conditions of onset):
• firstly, non-specific systemic signs, generally of sudden onset, such as asthenia, anorexia,
exhaustion, drowsiness, sometimes accompanied by repeated vomiting and abdominal
pain,
• secondly, a recurrence of epileptic seizures despite proper treatment compliance.
It is recommended that patients, or their families in the case of children, be informed that
they should immediately consult a doctor if this type of clinical picture occurs. In addition
to a physical examination, liver function tests should immediately be performed.
• Detection
During the first 6 months of treatment, there should be periodic monitoring of liver
function.
Tests reflecting protein synthesis and, in particular, PR (prothrombin rate) are the most pertinent
of the conventional tests. Confirmation of an abnormally low prothrombin rate, especially if
accompanied by other abnormal laboratory findings (significant reduction in fibrinogen and
coagulation factors, elevated bilirubin, elevated transaminase levels - see section 4.4 Special
warnings and special precautions for use), requires discontinuation of sodium valproate treatment (and, as a precautionary measure, salicylate derivatives if they are concomitantly prescribed, since they use the same metabolic pathway).
Pancreatitis:
Pancreatitis with a sometimes fatal outcome has been reported in exceptional cases. This can
be observed irrespective of age and treatment duration, with young children appearing to
be particularly at risk.
Pancreatitis with an unfavorable outcome is generally observed in young children or in patients
with severe epilepsy, brain damage or those taking multiple-agent antiepileptic treatment.
If pancreatitis is associated with hepatic insufficiency, the risk of a fatal outcome is
increased. 5
Interaction with other medicinal products:
Coadministration of this medicinal product with lamotrigine is not recommended (see section
4.5 Interaction with other medicinal products and other forms of interaction).
Precautions for use
Liver function tests should be performed before starting treatment (see section 4.3
Contraindications) and then periodically for the first 6 months, particularly in patients at risk
(see section 4.4 Special warnings and special precautions for use).
It should be emphasized that, as with most antiepileptics, an isolated and transient, moderate
elevation in transaminase levels may be observed, without any clinical signs, particularly at
the start of treatment. Should this occur, it is recommended that a more complete laboratory workup be performed (in particular, prothrombin rate), that the dosage be re-evaluated if necessary, and that the tests be repeated based on changes in the parameters.
In children under the age of 3, it is recommended that sodium valproate only be used as singleagent
treatment, after having weighed the therapeutic value against the risk of liver disease
and pancreatitis in patients belonging to this age group (see section 4.4 Special warnings and
special precautions for use).
Blood tests (complete blood count including platelets, bleeding time and coagulation parameters) are recommended prior to treatment and also before any surgery, and in the event of hematomas or spontaneous bleeding (see section 4.8 Undesirable effects).
In children, avoid the simultaneous prescription of salicylate derivatives, due to the risk of
hepatotoxicity (see "Special warnings") and the risk of bleeding.
In patients with renal insufficiency, elevated circulating valproic acid concentrations in the
blood should be taken into account and the dosage should be reduced accordingly.
In the event of acute abdominal pain or gastrointestinal signs such as nausea, vomiting and/ or anorexia, a diagnosis of pancreatitis must be considered and, in patients with elevated pancreatic enzymes, treatment should be discontinued, and the necessary alternative therapeutic measures implemented.
This medicinal product is not recommended in patients with urea cycle enzyme deficiencies.
A few cases of hyperammonemia associated with stupor or coma have been described in
these patients.
In children with a history of unexplained hepatic and gastrointestinal disturbances (anorexia,
vomiting, cytolytic episodes), episodes of lethargy or coma, mental retardation or with a family
history of neonatal or infant death, metabolic tests and, in particular, fasting and post-prandial
ammonemia tests must be performed prior to any valproate treatment.
Although it is recognized that this medicinal product only causes immunological disturbances
in exceptional cases, the benefit/risk ratio should be carefully weighed for use in patients with
systemic lupus erythematosus.
When initiating treatment, the patient should be informed of the risk of weight gain and of
the appropriate measures which are mainly dietary to be taken to minimize this effect.
When initiating treatment, it should be established that women of childbearing age are not
pregnant, and that effective contraception is being used before starting treatment (see section
4.6 Pregnancy and lactation).
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4.5 Interactions with other medicinal products and other forms of
interaction
The concomitant use of proconvulsant medicines, or those that lower the epileptogenic
threshold should be taken into account or may even be advised against or contraindicated
depending on the severity of the risk encountered. These medicines notably include most antidepressants (imipramine antidepressants, selective serotonin reuptake inhibitors) and benzodiazepines, neuroleptics (phenothiazines and butyrophenones), mefloquine (see below), bupropion, tramadol.

Contraindicated combinations (see section 4.3 Contraindications)
Mefloquine
In epileptic patients, risk of onset of epileptic seizures due to the increased metabolism of
valproic acid and the seizure-inducing effect of mefloquine.
St. John's Wort
Risk of reduced plasma concentrations and reduced efficacy of the anticonvulsant.
Inadvisable combination (see section 4.4 Special warnings and special precautions for use)
Salicylic derivatives
In children, avoid prescription of salicylic derivatives at the same time due to the risk of
hepatotoxicity (see section 4.4 Special warnings and special precautions for use) and the
risk of bleeding.
As a precautionary measure if concomitantly prescribed, salicylate compounds should also
be discontinued, since they use the same metabolic pathway.
Lamotrigine
Increased risk of serious skin reactions (Lyell's syndrome).

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Furthermore, an increase in lamotrigine plasma concentrations may occur (decreased hepatic
metabolism by valproate sodium).
If coadministration proves necessary, close clinical monitoring is required.
Combinations requiring special precautions for use
Aztreonam, Imipenem, Meropenem
Risk of onset of convulsive episodes due to reduced valproic acid plasma concentrations.
Clinical monitoring, plasma assays and possibly dose adjustment of the anticonvulsant during
treatment with the anti-infective agent and after its discontinuation.
Carbamazepine
Increased plasma concentrations of the active metabolite of carbamazepine with signs of
overdose. In addition, reduced valproic acid plasma concentrations due to increased hepatic
metabolism by carbamazepine.
Clinical monitoring, plasma assays and dose adjustment of both anticonvulsants.
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Felbamate
Increased valproic acid serum concentrations, with a risk of overdose.
Clinical and laboratory monitoring and possible valproate dose adjustment during treatment
with felbamate and after its discontinuation.
Phenobarbital, primidone
Increased plasma concentrations of phenobarbital or primidone with signs of overdose, due to
inhibition of hepatic metabolism, occurring most often in children. In addition, reduced valproic
acid plasma concentrations due to an increase in its hepatic metabolism by phenobarbital or
primidone.
Clinical monitoring for the first 15 days of combined administration and immediate reduction
of phenobarbital or primidone doses if any signs of sedation occur; in particular, plasma
concentrations of the two anticonvulsants should be monitored.
Phenytoin (and by extrapolation fosphenytoin)
Variations in phenytoin plasma concentrations. In addition, risk of reduced valproic acid plasma
concentrations due to increased hepatic metabolism by phenytoin.
Clinical monitoring, plasma assays and possible dose adjustment of both anticonvulsants.
Topiramate
Risk of the onset of hyperammonemia or encephalopathy, generally attributed to valproate
when administered concomitantly with topiramate.
Increased clinical and laboratory monitoring at the beginning of treatment and in the event
of symptoms suggesting this effect.
Combination to be taken into account
Nimodipine (oral route and, by extrapolation, injectable route)
Risk of enhanced hypotensive effect of nimodipine due to an increase in its plasma concentrations
(decreased metabolism by valproic acid).
Other forms of interaction
Oral contraceptives
As valproate has no enzyme-inducing activity, it does not reduce the efficacy of estrogenprogestogen
in women using hormonal contraception.
4.6 Pregnancy and lactation
In bipolar disorders, if pregnancy is planned, cessation of valporate prophylaxis should be
considered.
Pregnancy
In view of the available data, the use of sodium valproate is not recommended throughout
pregnancy and in women of childbearing age not using effective contraception.

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The risk of sodium valproate-induced malformations is 3 to 4 times higher in pregnant women
taking the medicinal product than that found in the general population, which is 3%. The most
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frequently observed malformations correspond to neural tube closure defects (approximately 2
to 3%), facial abnormalities, facial clefts, craniostenosis, cardiac defects, renal and urogenital
malformations, and deformities of the limbs.
Dosages greater than 1000 mg/day and combined use with other anticonvulsants are significant
risk factors for the occurrence of such malformations.
Current epidemiological data have not shown a reduction in the overall intelligence quotient
of children exposed to sodium valproate *in utero*. However, a slight decrease in verbal ability
and/or an increase in referrals to speech therapists or remedial support have been described
in these children. Furthermore, a few isolated cases of autism and related disorders have been
reported in children exposed to sodium valproate *in utero*.
Additional studies are necessary in
order to confirm or disprove all of these results.
If pregnancy is planned:
All steps will be taken to consider the use of other treatments if pregnancy is planned.
If the use of sodium valproate cannot be avoided (no other alternative):
It is advisable to administer the minimum effective daily dose and to preferably use prolongedrelease
forms or, if this is not possible, to divide the dosage into several doses so as to avoid
peak plasma valproic acid levels.
There is no evidence to date to support the efficacy of folic acid supplementation among
women exposed to sodium valproate during pregnancy.
However, given its beneficial effect in
other situations, supplementation may be proposed at a dose of 5 mg/day, one month before
and two months after conception. Screening for malformations will be identical whether or
not the patient has been taking folic acid.
During pregnancy:
If there is absolutely no option but to continue treatment with sodium valproate (no other
alternative), it is advisable to administer the minimum effective dosage, avoiding dosages
greater than 1000 mg/day if possible.
Screening for malformations will be identical whether or not the patient has been taking
folic acid.
Before birth:
Coagulation tests are to be performed, including in particular platelet count, fibrinogen levels
and coagulation time (activated partial thromboplastin time: aPTT) in the mother before
giving birth.
In neonates:
This medicinal product can cause a hemorrhagic syndrome in neonates which is not related
to a vitamin K deficiency.
Normal hemostasis tests in the mother do not rule out the possibility of hemostasis anomalies
in the neonate. Consequently a platelet count, a fibrinogen assay and an aPTT should be
performed in the neonate.
Furthermore, cases of hypoglycemia have been reported in neonates during the first week
following birth.
Lactation
Sodium valproate excretion in breast milk is low. However, given the questions raised by data
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relating to decreased verbal ability in infants exposed to the drug *in utero* (see above), patients
should preferably be advised not to breast-feed.
4.7 Effects on ability to drive and use machines
The attention of patients, particularly those who drive or use machines, must be drawn to
the risk of drowsiness, especially in the event of multiple-agent anticonvulsant therapy or
concomitant administration with other medicinal products that may increase drowsiness.
4.8 Undesirable effects
-- Exceptional cases of pancreatitis have been reported, requiring early treatment withdrawal.
Outcome may sometimes be fatal (see section 4.4 Special warnings and special precautions
for use).
-- Liver disease (see section 4.4 Special warnings and special precautions for use).
-- Teratogenic risk (see section 4.6 Pregnancy and lactation).
-- Rare cases of reversible Parkinsonian syndrome have been reported.
-- Very rare cases of cognitive disturbances of insidious and progressive onset, which may
progress as far as complete dementia and which are reversible a few weeks to a few months
following treatment withdrawal have been described.
-- Confusion or convulsions: a few cases of stupor or lethargy, sometimes leading to transient
coma (encephalopathy), either isolated or associated with a paradoxical increase in seizures,
have been observed with valproate, regressing on treatment discontinuation or dose reduction.
These states most often occur during multiple-agent therapy (phenobarbital in particular)
or following a sudden increase in valproate doses.
-- Some subjects may have gastrointestinal disturbances at the start of treatment (nausea, vomiting,
gastric pain, diarrhea), which generally resolve after a few days without discontinuation
of treatment.
-- Isolated and moderate hyperammonemia with no change in liver function tests is frequently
observed, especially in multiple-agent therapy, and should not lead to discontinuation of
treatment.
-- However, cases of hyperammonemia with neurological symptoms (that may even progress
to coma) have also been reported, and require additional tests (see section 4.4 Special
warnings and special precautions for use).
-- Very rare cases of hyponatremia.
-- Transient and/or dose-dependent unwanted effects have been reported: hair loss, fine
postural tremor and drowsiness.
-- Headaches have also been reported.
-- Uncommon cases of ataxia have been reported.
-- Cases of dose-dependent thrombocytopenia have been reported, generally discovered
systematically and without any clinical repercussions.
-- In patients with asymptomatic thrombocytopenia, if possible, based on the platelet level
and control of the epileptic disease, simply reducing the dosage of this medicinal product
usually leads to resolution of thrombocytopenia.
-- Cases of reduced fibrinogen or a prolongation in bleeding time, generally without clinical
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repercussions, have been reported, especially at high doses.
Valproate has an inhibitor
effect on the 2nd phase of platelet aggregation. More rarely, cases of anemia, macrocytosis,
leukopenia and, exceptionally, pancytopenia, have been reported.
Skin reactions such as exanthematous rashes have been

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observed. -- Exceptional cases of
Lyell's syndrome, Stevens-Johnson syndrome and polymorphous erythema have also been
reported.
-- Renal damage has been reported in exceptional cases.
-- Very rare cases of enuresis and urinary incontinence have been reported.
-- Reversible or non-reversible hearing impairment has been reported in exceptional cases.
-- Very rare cases of non-severe peripheral edema have been reported.
-- Cases of weight gain have been observed. Weight gain being a risk factor for polycystic
ovary syndrome, patients' weight should be carefully monitored (see section 4.4 Special
warnings and special precautions for use).
-- Amenorrhea and menstrual irregularities have also been reported.
4.9 Overdose
The presentation of massive acute toxicity usually consists of a calm coma, without movement,
which may be more or less deep, with muscular hypotonia, hyporeflexia, myosis, reduced
respiratory autonomy, and metabolic acidosis.
A few cases of intracranial hypertension related to cerebral oedema have been described.
The measures to be taken in a hospital setting are: gastric lavage if indicated, maintenance of
effective diuresis, cardiorespiratory monitoring. In very serious cases, extra-renal purification
may be performed if necessary.
The prognosis of such cases of toxicity generally is favorable, however a few deaths have
been reported.
5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Antiepileptic
ATC Code: N03AG01
Valproate produces its pharmacological effects mainly on the central nervous system.
These anticonvulsant properties are produced against very different types of convulsive seizures
in animals and epilepsies in humans.
Experimental and clinical studies on valproate suggest two types of anticonvulsant action.
The first is a direct pharmacological effect related to plasma concentrations of valproate and
concentrations in the brain.
The second is apparently an indirect effect probably related to metabolites of valproate which
persist in the brain or with changes in neurotransmitters or with direct membrane effects.
The hypothesis most generally recognized is that of gamma-aminobutyric acid (GABA) whose
concentrations increase after administration of valproate.
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Valproate decreases the duration of the intermediate phases of sleep with a concomitant
increase in slow-wave sleep.
In some *in vitro* studies, valproate sodium has been reported to possibly stimulate the replication
of HIV-1. However, this effect is modest, inconsistent, not dose-related and not documented
in humans.
5.2 Pharmacokinetic properties
The various pharmacokinetic studies conducted on valproate have shown that:
-- The bioavailability in the blood following oral administration is close to 100%.
-- Most of the substance is distributed in the blood and the rapid-exchange extra-cellular
fluids. It is also distributed in the CSF and the brain. CSF valproate concentrations are close
to those in the free plasma fraction.
-- The half-life is 15 to 17 hours.

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-- A therapeutic efficacy usually requires minimum serum concentrations of 40-50 mg/l,
with a wide range between 40 and 100 mg/l. If higher plasma levels prove necessary, the
expected benefits must be weighed against the risk of occurrence of unwanted effects,
particularly dose-dependent effects. However, levels remaining above 150 mg/l require a
reduction in the dose.
-- Plasma concentration at the steady state is reached within 3 to 4 days.
-- Binding of valproate to plasma proteins is very high. It is dose-dependent and saturable.
-- Valproate is excreted mainly in the urine after metabolization by glucuronic conjugation
and beta-oxidation.
-- Valproate is dialyzable, but hemodialysis affects only the unbound fraction of plasma
valproate (about 10%).
Valproate is not an inducer of enzymes involved in the cytochrome P 450 metabolic system,
contrary to most other antiepileptic agents, as a result, it does not accelerate its own breakdown,
nor that of other substances such as oestrogen-progestogens and oral anticoagulants.
When compared with valproate gastro-resistant forms, the prolonged-release form at equivalent
doses is characterized by:
-- disappearance of absorption lag time;
-- prolonged absorption;
-- identical bioavailability;
-- lower peak total and free plasma concentrations (Cmax about 25% lower with a relatively
stable plateau 4 to 14 hours post-administration); this "peak smoothing" effect yields
valproic acid concentrations that are steadier and more evenly distributed over a 24-hour
period: after twice-daily administration of the same dose, the magnitude of changes in
plasma valproate concentrations is reduced by half;
-- a more linear correlation between the dose and the total and free plasma concentration.
6. EXCIPIENTS
Ethylcellulose, methyl hydroxypropyl cellulose, anhydrous colloidal silica, hydrated colloidal
silica, saccharin sodium, hypromellose, macrogol 6000, talc, titanium dioxide, polyacrylate
30% dispersion. 12
7. STORAGE
Store below 25°C, in a dry place, well closed, protected from light and moisture.
8. PRESENTATION
SODIUM VALPROATE 500 MG tablets: 500 mg: 30 tablets
Each Film Coated Controlled Release Tablet Contains:

Sodium Valproate	BP	333mg
Valproic Acid	USP	145mg
Excipients		q.s.

Colour: Red Oxide Iron & Titanium Dioxide USP.

9. MANUFACTURER
Marketing Authorisation Holder
Manufactured in India by:
TAJ PHARMACEUTICALS LTD.
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