PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Depalept syrup 200 mg/5 ml Depalept 200 mg enteric-coated tablets Depalept 500 mg enteric-coated tablets Depalept syrup

Sodium Valproate 200 mg/5 ml Depalept 200 mg

Enteric-coated tablets, each tablet contains: Sodium Valproate 200 mg

Enteric-coated tablets, each tablet contains:

Depalept 500 mg

Sodium Valproate 500 mg Inactive ingredients and allergens in the preparation - see section 6 and section 2

"Important information about some of the ingredients of the medicine". Read the entire leaflet carefully before using

the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

pass it on to others. It may harm them even if it seems to you that their

medical condition is similar. The medicine is not intended for children weighing less than 17 kg.

Depalept may severely harm the fetus when taken during pregnancy

Neonates born to mothers who have taken valproate during pregnancy are at an increased risk of serious developmental disorders (mental and physical) and behavioral disorders (approximately 30-40% of cases) and/or congenital malformations (approximately 11%

If you are a woman of childbearing age or if you | | Special warnings regarding the use of the are pregnant, the doctor will prescribe valproate for you only if other treatments are unsuitable. Women of childbearing age should use effective contraception while taking this medicine. If despite using contraception you become pregnant unintentionally, contact you doctor immediately in order to discuss the options for alternative therapy, if possible. Do not stop using the medicine without consulting the treating doctor, because your condition may worsen.

preparation has a patient safety information card. This card contains important safety information that you must know before starting treatment life-threatening with Depalept and during the treatment, and act information card and the patient leaflet before

You should consult a doctor immediately if the following effects appear: · Sudden tiredness, loss of appetite, fatigue,

weakness This medicine is an anticonvulsant, and it is administered for treatment of certain types of Therapeutic class: The active ingredient belongs

2. Before using the medicine:

In addition to the leaflet, the Depalept

accordingly. Please review the patient

the card for further review if necessary

starting to use the preparation. You should keep

I. What is the medicine intended for?

☑ Do not use this medicine if you:

· Are sensitive (allergic) to the active ingredient or to any component of the medicine (see section 6 – Additional information). Are sensitive to another medicine of the valproate family (valproate semisodium,

valpromide). Have a liver disease (acute or chronic This medicine has been prescribed for you. Do not

> Or someone in your family have had or currently has a serious liver disease. especially if it was caused by the use of medications

Have hepatic porphyria (a hereditary liver)

 Have a genetic problem causing a mitochondrial disorder, e.g. Alpers-Huttenlocher syndrome.

· Have a metabolic disorder, such as urea cycle normal body weight. Are currently taking any of the following

medicines o St. John's Wort (for treatment of

medicine

 Do not give this medicine to girls, adolescent girls, women of childbearing age and pregnant women, unless alternative treatments have been found to be unsuitable.

 Women of childbearing age who are treated with this medicine should use effective contraception. If a woman taking this medicine plans to become pregnant, she should consult her doctor regarding the possibility of receiving an alternative treatment.

This medicine may, in very rare cases, cause damage to the liver (hepatitis) or pancreas (pancreatitis), which may be severe and

Your doctor will refer you to perform blood tests for evaluation of liver function, especially during the first 6 months of treatment.

drowsiness, swelling in the legs, general

Repeated vomiting, nausea, abdominal pain, vellowing of the skin or the whites of the eyes (iaundice).

You suffer from a kidney disease (renal

Recurrence of epileptic seizures, even though to the group of anticonvulsants. you are taking the medicine correctly.

Before treatment with Depalept, inform your doctor if:

insufficiency), systemic lupus erythematosus treatment of depression or hereditary enzyme deficiency, especially enzyme deficiency in the urea cycle which ma cause elevation of ammonium blood levels, or a genetic problem that causes a mitochondrial disorder (including members of your family).

Before undergoing any type of surgery, inform the medical staff that you are taking Depalept. Before starting treatment, the doctor will check that you are not pregnant and that you are using

contraception. As with other antiepileptic medicines, taking this medicine may worsen the seizures or increase their frequency. You may even experience a different kind of seizures. If these effects occur,

consult a doctor immediately. This medicine may cause weight gain. Consult your doctor regarding methods for maintaining

Taking anticonvulsants may increase the risk for suicidal actions or thoughts. You and your family members must pay attention to changes in mood, behavior patterns and actions. Watch felbamate, phenytoin, fosphenytoin, primidone, for signs indicating risk of suicide, such as: talking or thinking about wanting to hurt yourself, introversion and withdrawal from family and friends, depression or worsening of existing depression, preoccupation with the subject of death, abandoning or giving away prized possessions. If thoughts of this kind occur, refer nimodipine

to the doctor immediately. If you suffer from carnitine palmitovltransferase (CPT) type II enzyme deficiency (hereditary metabolic disease), there is an increased risk of muscle breakdown when taking Depalept.

Tell your doctor if you are experiencing symptoms such as tremor, limb rigidity and difficulty walking (extrapyramidal disorders) or

disturbances of memory or cognitive function. The doctor will examine whether they are caused • Salicylates (including aspirin) by an existing condition or by Depalept. Stopping • Cannabidiol (for treatment of epilepsy and other • Eye deformities which can affect vision have the treatment may be necessary.

When treating children, tell your doctor if your child Especially in children under the age of 3, avoid the is taking additional treatment for epilepsy or has a use of medicines containing salicylates (including neurological or metabolic disease or severe forms aspirin) during the treatment with the medicine. of epilepsy.

■ Tests and follow-up Before starting treatment and during the first six months of treatment with this medicine, you should. Drinking alcoholic beverages is not recommended. perform blood tests for liver functions.

■ Drug interactions Certain medicines affect the activity of valproate. and vice versa. Do not take Depalept if you are taking the

ollowing medicines: St. John's Wort – an herbal remedy for the

Jnless the doctor has instructed you otherwise, do not take Depalept if you are Do not take Depalent: taking, have recently taken or may take the

Lamotrigine (another medicine for the treatment Medicines of the penem group (carbapenems) (a group of antibiotics for treatment of bacterial

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are

> Medicines containing acetazolamide (for lowering) intraocular pressure or carbon dioxide levels in

> > Antibiotics (medicines containing aztreonam or Other medicines for the treatment of epilepsy (medicines containing carbamazepine,

phenobarbital, rufinamide, topiramate or zonisamide). Nimodipine - used for prevention of complications that may occur following cerebral bleeding. Depalept may increase the effect of

Medicines containing estrogen (including certain types of birth control pills). Propofol (anesthetic medicine).

 Medicines containing zidovudine (for the treatment of HIV).

 Medicines containing lithium (for mood) stabilization).

 Medicines containing metamizole/dipyrone (for treatment of fever and pain).

II Use of the medicine and food

It is best to take the medicine during meals. during treatment with this medicine.

■ Pregnancy, breastfeeding and fertility Valproate is harmful to the fetus if taken during pregnancy, therefore:

 If you are a woman of childbearing age, the doctor will prescribe this medicine for you only if alternative treatments were found unsuitable. Read the patient safety information card.

 There is some evidence that children exposed to valproate in utero are at an If you are pregnant, unless alternative increased risk of developing symptoms treatments have been found to be unsuitable. If you are a woman of childbearing age, the of attention deficit hyperactivity disorders doctor will prescribe this medicine for you

only if alternative treatments were found Before giving you the medicine, the doctor will explain to you the possible risks to your baby in the case of exposure to valproate Parents or caregivers of girls that are treated during pregnancy. If you later decide that you with valproate should inform the doctor as soon wish to become pregnant, do not stop taking the as their daughter starts menstruating. medicine or your contraception before consulting with the doctor and considering the option of

Certain types of birth control pills (estrogencontaining birth control pills) may reduce the changing your treatment, if possible. levels of valproate in the blood. Consult the Starting treatment with Depalept doctor to determine which contraception will be If this is the first time Depalept has been the most suitable for you.

malformations, which affect various organs and

prescribed for you, the doctor will explain to you Risks of valproate when taken during pregnancy: the possible risks for your baby in the case of Valproate may harm the fetus when taken during exposure to valproate during pregnancy. If you are pregnancy. The risk increases with the dosage, a woman of childbearing age, you should use but it exists with all dosages, even when effective contraception while using the valproate is taken in combination with other medicine. Consult a gynecologist about effective antiepileptic medicines. contraception. Children exposed to valproate in utero are at

high risk for severe congenital malformations and Important issues: Before starting the treatment, the doctor will developmental disorders. make sure that there are no other alternative The most common congenital malformations reported include spina bifida (a developmental treatments suitable for you. Pregnancy should be ruled out before starting malformation in which the spine does not

the treatment. develop properly), facial, upper lip, palate Make sure that you are using effective and skull malformations; malformations of the contraception heart, kidneys, urinary tract and genitals; limb A routine follow-up (at least annually) should be deformities and involvement of multiple other carried out by a doctor. The doctor will make sure congenital malformations associated with valproate

body parts. Congenital malformations may lead that you are aware of and understand the risks and Important issues:

to disabilities which may be severe. Hearing disorders and hearing impairment have If you are planning to become pregnant, been reported in children exposed to valproate inform the doctor before you stop taking your

in utero contraception. Consult the doctor immediately if you are been reported in children exposed to valproate pregnant or think you might be pregnant.

• Taking valproate during pregnancy increases the Continuing Depalept treatment when you are risk of giving birth to a child with congenital not planning a pregnancy malformations that will require medical treatment. Make sure you are using effective It has been found that in women taking valproate. **contraception throughout the treatment period.** around 11 babies out of 100 are born with Consult a gynecologist about effective congenital malformations, compared with 2-3 contraception.

 Approximately 30-40% of pre-school children
 The treating doctor should routinely (at least whose mothers have taken valproate during annually) evaluate if there are more suitable pregnancy may have problems with early treatment alternatives for you. childhood development, such as: delay in Make sure that you are using effective starting to walk and talk, lower intellectual contraception ability, language and memory difficulties.

developmental disorders. Do not stop using the • A routine follow-up (at least annually) should be medicine before consulting with the treating doctor. Do not breastfeed while taking Depalept, unless Autistic spectrum disorders are more often carried out by a doctor. The doctor will make sure as your condition may worsen. If you are taking diagnosed in children exposed to valproate that you are aware of and understand the risks Depalept and you think that you might be and recommendations related to taking valproate pregnant, contact your doctor immediately. during pregnancy. The doctor will instruct you further.

developmental disorders.

doctor before becoming pregnant.

the fetus as much as possible.

during treatment with Depalept".

reduce the risk of spina bifida and early

Do not stop using the medicine or your

· If you are planning to become pregnant, The doctor will make every effort to discontinue inform the doctor before you stop taking your treatment with Depalept and to evaluate all contraception. alternative treatments.

To the extent possible, consult your treating

contraception before consulting with your doctor.

Your doctor will make every effort to find alternative

treatments so that the pregnancy will be as normal

as possible, while reducing the risks to you and to

Your doctor will make every effort to stop the

treatment with Depalept as early as possible

before you become pregnant, to ensure that your

disease is stabilized. In exceptional cases, when

this is impossible, read the section "Pregnancy

Consult your doctor regarding taking folic acid

miscarriages, that exists with all pregnancies.

when planning a pregnancy. Taking folic acid can

However, it is unlikely that it will reduce the risk of

Consult the doctor immediately if you are In exceptional cases, when Depalept is the only pregnant or think you might be pregnant. possible treatment during pregnancy: Treatment with Depalept if you are planning a Your doctor will be able to refer you to a

Children exposed to valproate in utero are at high pregnancy under valproate. risk for severe congenital malformations and The doctor will try to reduce the dosage of valproate.

 You will be closely monitored to manage your health condition and to check the development ingredients of the medicine of the fetus.

pregnancy. The child will be closely monitored

the appropriate treatment for him, as early as

possible as needed

· Consult your doctor regarding taking folic acid Taking folic acid can reduce the risk of spina bifida and early miscarriages, that exists with all pregnancies. However, it is unlikely that it Amount of sorbitol in each 5 ml: 655 mg. Sorbitol is will reduce the risk of congenital malformations a source of fructose. If there is a known intolerance associated with valproate use.

to certain sugars, or a diagnosis of hereditary Before delivery: The doctor will prescribe certain fructose intolerance (HFI), consult your doctor vitamins for you, so that this medicine will not before taking this medicine. cause bleeding during the first days of your baby's life or bone deformations. After delivery: Your baby may receive a vitamin k

The preparation contains parabens. These substances may cause an allergic reaction (even some time after taking them). injection to prevent bleeding. The child: Inform the pediatrician that you The preparation contains sucrose and may were treated with valproate during your damage the teeth. If you were told by a doctor that

you are suffering from sensitivity to certain sugars for neurological development in order to provide you should consult a doctor before taking the

Important issues:

recommendations related to taking valproate during

• Do not stop taking Depalept unless your doctor Consult the doctor immediately if you are pregnant or think you might be pregnant.

 Do not stop using contraception before you have
 Do not stop taking Depalept unless your doctor consulted with your doctor, and worked together told you to. on a treatment plan that will enable you to control • The doctor will evaluate all of the options for your epilepsy and reduce the risk to the fetus. stopping the treatment

 Consult with your doctor. The doctor will make The doctor will give you the full information sure that you are aware of and understand the risks and recommendations related to taking during pregnancy, including the risk for valproate during pregnancy. congenital defects and developmental disorders Your doctor will make every effort to stop the (cognitive, physical and behavioral) in children.

treatment with Depalept as early as possible

· Consult the doctor immediately if you are

pregnant or think you might be pregnant.

Pregnancy during treatment with Depalept

risk for severe congenital malformations and

Children exposed to valproate in utero are at high

before you become pregnant.

prenatal monitoring in order to detect possible malformations. Inform the pediatrician that you were treated with valproate during your pregnancy. The child will be closely monitored for neurological

Make sure you are referred to a specialist for

development Breastfeeding the doctor recommends otherwise. Consult the

doctor or pharmacist before starting treatment with any medicine. Do not exceed the recommended dose. ■ Driving and operating machinery

Use of this medicine may impair alertness. less than 17 kg. especially if taken in combination with other antiepileptic medicines or medicines that cause

If you experience this effect or if your epilepsy is not vet under control and vou continue to suffer measure the correct amount of medicine. specialist who can provide consultation regarding from seizures, do not drive or operate dangerous You should use the measuring syringe to measure

machinery. the correct amount of medicine. Children should be cautioned against riding a Child-proof safety caps have significantly reduced bicycle or playing near a road etc.

the number of poisoning incidents caused by I Important information about some of the medicines each year. However, if you find it difficult to open the package, you can refer to a pharmacist Depalept syrup: Amount of sodium in each 5 n to ask to have the safety mechanism removed and approximately 29 mg, which is equivalent to 1.5% to turn the cap into a regular, easy-to-open cap. of the maximum recommended daily intake in Tablets: the tablet should be swallowed whole with

a large glass of water. Pulverization/halving/chewing: The tablets are enteric-coated. In order to maintain its maximum efficacy, the tablet should not be halved or

If you have accidentally taken a higher dosage you may suffer from the following symptoms: coma, muscle weakness, decreased reflexes, constriction of the pupils, breathing impairment, metabolic acidosis, decreased blood pressure and

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

The preparation contains Ponceau 4R which may If you have forgotten to take this medicine at Additional side effects: cause allergic reactions.

Depalept 200 mg, Depalept 500 mg: Amount of sodium in each tablet; approximately 28 mg, 70 mg doctor respectively, which is equivalent to 1.4%, 3.5% Follow the treatment as recommended by the respectively of the maximum recommended daily intake in adults

regarding the risks involved with using Depalept 3. How should you use the medicine Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be

might be at an increased risk for seizures. determined by the doctor only. Before discontinuing the treatment you should The doctor may recommend to divide the required discuss the consequences with your doctor. dose to twice a day. Do not take medicines in the dark! Check the

Patients with kidney failure: the doctor may decide label and the dose every time you take the to adjust the dosage.

It is best to take the medicine during meals. This medicine should be used at set intervals as determined by the treating doctor. pharmacist.

4. Side effects This medicine is not intended for children weighing As with any medicine, using Depalept may cause side effects in some users. Do not be alarmed **Duration of treatment:** Do not stop treatment with

when reading the list of side effects. You may not the medicine without consulting the doctor. experience any of them. Method of administration Contact the doctor immediately if you Syrup: you should use the measuring cup to

experience the following side effects: Damage to the liver (hepatitis) or pancreas (pancreatitis), which may be severe and lifethreatening. These effects can start abruptly with tiredness, loss of appetite, fatigue, somnolence,

should be done gradually.

not according to your doctor's instruction, you

nausea, vomiting and intestinal pain. hormone) An allergic reaction which includes: Sudden swelling of the face and/or neck -10 out of 1,000 users: that causes difficulty breathing and is lifethreatening (angioedema).

Severe allergic reaction that includes symptoms such as: fever, skin rash, enlarged lymph nodes, liver damage, kidney damage, abnormal blood test results, such as: increase in certain white blood cells (eosinophils).

Emergence of a rash on the skin, sometimes accompanied by the appearance of blisters that may involve the mouth area (ervthema multiforme), emergence of blisters with detachment of the skin that can rapidly spread to the entire body and be life-threatening (Lyell's syndrome. Stevens-Johnson syndrome).

Additional possible side effects: Congenital malformations and physical and

mental development disorders (see the section "Pregnancy, breastfeeding and fertility").

the required time, do not take a double dose. Take Very common side effects – side effects that occur the next dose at the scheduled time and consult a in more than one out of ten users: Nausea

doctor. Even if there is an improvement in your Common side effects - side effects that occur in health, do not stop treatment with Depalept without 1-10 out of 100 users: At the start of the treatment: vomiting, abdominal consulting the doctor. pain, diarrhea If you stop taking Depalept

 Weight gain Do not stop treatment with the medicine without Headaches consulting the doctor. Discontinuation of treatment Somnolence

 Seizures If you discontinue Depalept treatment abruptly or Memory impairment Confusion, aggressiveness, nervousness,

> attention disorders, hallucinations (seeing or nearing non-existing things) Extrapyramidal disorders (symptoms include:

tremor, limb rigidity and difficulty walking)* Urinary incontinence

medicine. Wear glasses if you need them. Quick and involuntary eve movements If you have any other questions regarding use Hearing impairment of the medicine, consult the doctor or the Gum problems, especially overgrowth of the

Pain and swelling in the mouth, ulcers in the

mouth and a burning sensation in the mouth ovaries) Hair loss

 Irregular menstrual periods Bleeding

gums (gingival hyperplasia)

Nausea or dizziness

 Nails and nail bed disorders Decrease in red blood cell count (anemia) and severe (rhabdomyolysis) platelet count (thrombocytopenia)

 Low levels of sodium in the blood (hyponatremia. a symptom of improper secretion of antidiuretic

(macrocytosis), a significant decrease in white Uncommon side effects - side effects that occur in blood cell count (agranulocytosis) Alertness impairment which may develop into

a temporary coma, with remission after dose Difficulty in movement synchronization partial thromboplastin time and INR time)

 Sensation of numbness/tingling in the hands and biotinidase

consulting with the doctor first.

Increased ammonium blood levels Double vision · Hair problems (changes in the hair structure,

color or growth) Rash or hives on the skin

Reversible parkinsonism*

 Hyperandrogenism (symptoms include excessive hairiness, especially in women, development of masculine features in a woman, acne)

reduction or treatment cessation

 Swelling of the extremities (edema) Lack of menstrual period

> Worsening and increased frequency of convulsions. Onset of a different type of seizures frequently in children or are more severe

Breathing difficulties and pain due to

Decrease in the numbers of all blood cells: behavior that is not within the norm, hyperactivity Ltd., 3 Hakidma St., Kirvat Malachi 83057, Israel. white blood cells, red blood cells and platelets and learning disorders. (pancytopenia), decrease in the number of white If a side effect occurs, if one of the side effects with the Ministry of Health guidelines. blood cells (leukopenia) Cases of bone damage such as bones that

become more fragile (osteopenia), decreased bone density (osteoporosis) and fractures, have been reported. Consult your doctor or pharmacist if you are receiving long-term treatment with epilepsy medicines, if you have or have previously had osteoporosis or if you are taking corticosteroids https://sideeffects.health.gov.il/ Inflammation of blood vessels

Rare side effects - side effects that occur in 1-10 out of 10,000 users:

Enuresis Sterility in men, generally reversible 3 months at least after treatment is discontinued, and

potentially reversible after dosage reduction. D not discontinue the treatment without consulting with the doctor first Impaired functioning of the ovaries (polycystic)

refers to the last day of that month. Behavioral disturbances, increased psychomotor

activity, learning disabilities · An autoimmune reaction with joint pain, skin rash and fever (systemic lupus erythematosus)

 Underactive thyroid gland (hypothyroidism) Muscle pain, muscle weakness which may be

Weight gain

 Kidnev damage (kidnev failure, tubulointerstitial nephritis. Fanconi syndrome) also contains: Increase in the size of red blood cells Depalept syrup:

Decreased and irregular blood cell production Decrease in coagulation factors, abnormal coagulation test results (such as: increase in

Decrease in the levels of vitamin B8 (biotin)/

Dementia and cognitive disorders* that appear

gradually and recede several weeks to several months after stopping treatment Do not discontinue the treatment without

*Symptoms may include signs in brain imaging Decrease in body temperature (hypothermia) (atrophy).

> Additional side effects in children: Some side effects of valproate occur more

inflammation of the protective membranes of the damage, inflammation of the pancreas. lungs (pleural effusion) aggressiveness, nervousness, attention disorders, holder/manufacturer: CTS Chemical Industries

> worsens, or if you suffer from a side effect not Registration numbers of the medicines in the mentioned in this leaflet, consult your doctor. national drug registry of the Ministry of Health: Side effects may be reported to the Ministry of Depalept syrup: 337222644 Health by clicking on the link "Report side effects"
>
> Depalept 200 mg enteric-coated tablets due to medicinal treatment" found on the Ministry 483023229 of Health website homepage (www.health.gov.il), Depalept 500 mg enteric-coated tablets which will direct you to the online form for reporting 337122348 side effects, or by clicking on the following link:

compared to adults. These effects include liver

5. How to store the medicine? Avoid poisoning! This medicine and any other

medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date

Storage conditions

Syrup: Store at a temperature below 25°C. Can be used for up to two months from opening. Tablets: Store in the original package in order to protect from light and moisture, in a dry place, at a temperature below 25°C. Can be used for up to two months from opening.

6. Additional information

In addition to the active ingredient, the medicine

Sucrose, sorbitol solution 70%, sodium methyl hydroxybenzoate, saccharin sodium, ponceau 4R cherry flavour, sodium propyl hydroxybenzoate, purified water.

Depalept 200 mg and Depalept 500 mg: Purified talc, povidone (K25), maize starch cellulose acetate phthalate. Calcium silicate polyethylene glycol 400, diethyl phthalate, povidone (K90), titanium dioxide micronized.

glass bottle containing a cherry-red colored syrup

magnesium stearate. Depalept 500 mg: Iron yellow oxide E172 What does the medicine look like and what are the contents of the package: Depalept syrup: a transparent, amber-colored

Depalept 200 mg enteric-coated tablets: a glass jar containing 40 white, round, coated tablets. Depalept 500 mg enteric-coated tablets: a glass jar



containing 40 white round coated tablets

Name and address of the marketing authorization

This leaflet was revised in 07/2023 in accordance