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
Depalept 500 mg
Enteric-coated tablets, each tablet contains:
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.
This medicine has been prescribed for you. Do not 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.

Warning
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% of cases).
If you are a woman of childbearing age or if you 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 your 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.

In addition to the leaflet, the Depalept preparation has a patient safety information card.
This card contains important safety information that you must know before starting treatment with Depalept and during the treatment, and act accordingly. Please review the patient information card and the patient leaflet before starting to use the preparation. You should keep the card for further review, if necessary.

1. What is the medicine intended for?

This medicine is an anticonvulsant, and it is administered for treatment of certain types of epilepsy.
Therapeutic class: The active ingredient belongs to the group of anticonvulsants.

2. Before using the medicine:

☒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 hepatitis).
- 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 disease).
- Have a genetic problem causing a mitochondrial disorder, e.g. Alpers-Huttenlocher syndrome.
- Have a metabolic disorder, such as urea cycle disorder.
- Are currently taking any of the following medicines:
  - St. John's Wort (for treatment of depression).

ℹ Special warnings regarding the use of the 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 life-threatening.
Your doctor will refer you to perform blood tests for evaluation of liver function, especially during the first 6 months of treatment.
You should consult a doctor immediately if the following effects appear:

- Sudden tiredness, loss of appetite, fatigue, drowsiness, swelling in the legs, general weakness.
- Repeated vomiting, nausea, abdominal pain, yellowing of the skin or the whites of the eyes (jaundice).
- Recurrence of epileptic seizures, even though you are taking the medicine correctly.

- **Before treatment with Depalept, inform your doctor if:**
  - You suffer from a kidney disease (renal insufficiency), systemic lupus erythematosus or hereditary enzyme deficiency, especially enzyme deficiency in the urea cycle which may cause elevation of ammonium blood levels, or a genetic problem that causes a mitochondrial disorder (among 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 normal body weight.
- 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 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 to the doctor immediately.
- If you suffer from carnitine palmitoyltransferase (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 by an existing condition or by Depalept. Stopping the treatment may be necessary.

When treating children, tell your doctor if your child is taking additional treatment for epilepsy or has a neurological or metabolic disease or severe forms of epilepsy.
ℹ Tests and follow-up
Before starting treatment and during the first six months of treatment with this medicine, you should perform blood tests for liver functions.
ℹ Drug interactions
Certain medicines affect the activity of valproate, and vice versa.
Do not take Depalept if you are taking the following medicines:
- St. John's Wort – an herbal remedy for the treatment of depression.

Unless the doctor has instructed you otherwise, do not take Depalept if you are taking, have recently taken or may take the following medicines:
- Lamotrigine (another medicine for the treatment of epilepsy).
- Medicines of the penem group (carbapenems) (a group of antibiotics for treatment of bacterial infections).

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 taking:
- Medicines containing acetazolamide (for lowering intraocular pressure or carbon dioxide levels in the blood).
- Antibiotics (medicines containing aztreonam or rifampicin).
- Other medicines for the treatment of epilepsy (medicines containing carbamazepine, felbamate, phenytoin, fosphenytoin, primidone, phenobarbital, rufinamide, topiramate or zonisamide).
- Nimodipine - used for prevention of complications that may occur following cerebral bleeding. Depalept may increase the effect of nimodipine.
- 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).
- Salicylates (including aspirin).
- Cannabidiol (for treatment of epilepsy and other diseases).

Especially in children under the age of 3, avoid the use of medicines containing salicylates (including aspirin) during the treatment with the medicine.
ℹ Use of the medicine and food
It is best to take the medicine during meals.
ℹ Use of the medicine and alcohol consumption
Drinking alcoholic beverages is not recommended during treatment with this medicine.
ℹ 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.**

Do not take Depalept:
- If you are pregnant, unless alternative treatments have been found to be unsuitable.
- If you are a woman of childbearing age, the doctor will prescribe this medicine for you only if alternative treatments were found unsuitable.

- Parents or caregivers of girls that are treated with valproate should inform the doctor as soon as their daughter starts menstruating.
- Certain types of birth control pills (estrogen-containing birth control pills) may reduce the levels of valproate in the blood. Consult the doctor to determine which contraception will be the most suitable for you.

Risks of valproate when taken during pregnancy:
- Valproate may harm the fetus when taken during pregnancy. The risk increases with the dosage, **but it exists with all dosages**, even when valproate is taken in combination with other antiepileptic medicines.
- Children exposed to valproate in utero are at high risk for severe congenital malformations and developmental disorders.
- The most common congenital malformations reported include *spina bifida* (a developmental malformation in which the spine does not develop properly), facial, upper lip, palate and skull malformations; malformations of the heart, kidneys, urinary tract and genitals; limb deformities and involvement of multiple other malformations, which affect various organs and body parts. Congenital malformations may lead to disabilities which may be severe.
- Hearing disorders and learning impairment have been reported in children exposed to valproate in utero.
- Eye deformities which can affect vision have been reported in children exposed to valproate in utero.
- Taking valproate during pregnancy increases the risk of giving birth to a child with congenital malformations that will require medical treatment. It has been found that in women taking valproate, around **11 babies out of 100 are born with congenital malformations, compared with 2-3 babies out of 100 in the general population.**
- **Approximately 30-40% of pre-school children whose mothers have taken valproate during pregnancy may have problems with early childhood development, such as: delay in starting to walk or talk, lower intellectual ability, language and memory difficulties.**
- **Autistic spectrum disorders are more often diagnosed in children exposed to valproate in utero.**
- **There is some evidence that children exposed to valproate in utero are at an increased risk of developing symptoms of attention deficit hyperactivity disorders (ADHD).**
- Before giving you the medicine, **the doctor will explain to you the possible risks to your baby in the case of exposure to valproate during pregnancy.** If you later decide that you wish to become pregnant, do not stop taking the medicine or your contraception before consulting with the doctor and considering the option of changing your treatment, if possible.

Starting treatment with Depalept
If this is the first time Depalept has been prescribed for you, the doctor will explain to you the possible risks for your baby in the case of exposure to valproate during pregnancy. **If you are a woman of childbearing age, you should use effective contraception while using the medicine.** Consult a gynecologist about effective contraception.
Important issues:
- Before starting the treatment, the doctor will make sure that there are no other alternative treatments suitable for you.
- Pregnancy should be ruled out before starting the treatment.
- Make sure that you are using effective contraception.
- A routine follow-up (at least annually) should be carried out by a doctor. The doctor will make sure that you are aware of and understand the risks and recommendations related to taking valproate during pregnancy.
- If you are planning to become pregnant, inform the doctor before you stop taking your contraception.
- Consult the doctor immediately if you are pregnant or think you might be pregnant.

Continuing Depalept treatment when you are not planning a pregnancy
Make sure you are using effective contraception throughout the treatment period. Consult a gynecologist about effective contraception.
Important issues:
- The treating doctor should routinely (at least annually) evaluate if there are more suitable treatment alternatives for you.
- Make sure that you are using effective contraception.
- A routine follow-up (at least annually) should be carried out by a doctor. The doctor will make sure that you are aware of and understand the risks and recommendations related to taking valproate during pregnancy.
- If you are planning to become pregnant, inform the doctor before you stop taking your contraception.
- Consult the doctor immediately if you are pregnant or think you might be pregnant.

Treatment with Depalept if you are planning a pregnancy
Children exposed to valproate in utero are at high risk for severe congenital malformations and developmental disorders.
To the extent possible, consult your treating doctor before becoming pregnant.
Do not stop using the medicine or your 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 the fetus as much as possible.
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 during treatment with Depalept**".
Consult your doctor regarding taking folic acid when planning a pregnancy. Taking folic acid can reduce the risk of *spina bifida* and early miscarriages, that exists with all pregnancies. However, it is unlikely that it will reduce the risk of congenital malformations associated with valproate use.
Important issues:
- Do not stop taking Depalept unless your doctor told you to.
- Do not stop using contraception before you have consulted with your doctor, and worked together on a treatment plan that will enable you to control your epilepsy and reduce the risk to the fetus.
- Consult with your doctor. The doctor will make sure that you are aware of and understand the risks and recommendations related to taking valproate during pregnancy.
- Your doctor will make every effort to stop the treatment with Depalept as early as possible before you become pregnant.
- Consult the doctor immediately if you are pregnant or think you might be pregnant.

Pregnancy during treatment with Depalept
Children exposed to valproate in utero are at high risk for severe congenital malformations and developmental disorders. Do not stop using the medicine before consulting with the treating doctor, as your condition may worsen. **If you are taking Depalept and you think that you might be pregnant, contact your doctor immediately.**
- The doctor will instruct you further.
- The doctor will make every effort to discontinue treatment with Depalept and to evaluate all alternative treatments.

In exceptional cases, when Depalept is the only possible treatment during pregnancy:
- Your doctor will be able to refer you to a specialist who can provide consultation regarding pregnancy under valproate.
- 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 of the fetus.
- 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 will reduce the risk of congenital malformations associated with valproate use.
- Before delivery: The doctor will prescribe certain vitamins for you, so that this medicine will not cause bleeding during the first days of your baby's life or bone deformations.
- After delivery: Your baby may receive a vitamin K injection to prevent bleeding.
- The child: Inform the pediatrician that you were treated with valproate during your pregnancy. The child will be closely monitored for neurological development in order to provide the appropriate treatment for him, as early as possible, as needed.

Important issues:
- Consult the doctor immediately if you are pregnant or think you might be pregnant.
- Do not stop taking Depalept unless your doctor told you to.
- The doctor will evaluate all of the options for stopping the treatment.
- The doctor will give you the full information regarding the risks involved with using Depalept during pregnancy, including the risk for congenital defects and developmental disorders (cognitive, physical and behavioral) in children.
- Make sure you are referred to a specialist for 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 development.

Breastfeeding
Do not breastfeed while taking Depalept, unless the doctor recommends otherwise. Consult the doctor or pharmacist before starting treatment with any medicine.
ℹ Driving and operating machinery
Use of this medicine may impair alertness, especially if taken in combination with other antiepileptic medicines or medicines that cause drowsiness.
If you experience this effect or if your epilepsy is not yet under control and you continue to suffer from seizures, do not drive or operate dangerous machinery.
Children should be cautioned against riding a bicycle or playing near a road etc.
ℹ Important information about some of the ingredients of the medicine
Depalept syrup: Amount of sodium in each 5 ml: approximately 29 mg, which is equivalent to 1.5% of the maximum recommended daily intake in adults.
Amount of sorbitol in each 5 ml: 655 mg. Sorbitol is a source of fructose. If there is a known intolerance to certain sugars, or a diagnosis of hereditary fructose intolerance (HFI), consult your doctor before taking this medicine.
The preparation contains parabens. These substances may cause an allergic reaction (even some time after taking them).
The preparation contains sucrose. It may damage the teeth. If you were told by a doctor that you are suffering from sensitivity to certain sugars, you should consult a doctor before taking the medicine.
The preparation contains Ponceau 4R, which may cause allergic reactions.
Depalept 200 mg, Depalept 500 mg: Amount of sodium in each tablet: approximately 28 mg, 70 mg respectively, which is equivalent to 1.4%, 3.5% respectively of the maximum recommended daily intake in adults.

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 determined by the doctor only. The doctor may recommend to divide the required dose to twice a day.
It is best to take the medicine during meals.
This medicine should be used at set intervals as determined by the treating doctor.
Do not exceed the recommended dose.
This medicine is not intended for children weighing less than 17 kg.
Duration of treatment: Do not stop treatment with the medicine without consulting the doctor.
Method of administration
Syrup: you should use the measuring cup to measure the correct amount of medicine.
You should use the measuring syringe to measure the correct amount of medicine.
Child-proof safety caps have significantly reduced the number of poisoning incidents caused by medicines each year. However, if you find it difficult to open the package, you can refer to a pharmacist to ask to have the safety mechanism removed and to turn the cap into a regular, easy-to-open cap.
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 crushed.
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 shock.
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.
If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.
Follow the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with Depalept without consulting the doctor.
If you stop taking Depalept
Do not stop treatment with the medicine without consulting the doctor. Discontinuation of treatment should be done gradually.
If you discontinue Depalept treatment abruptly or not according to your doctor's instruction, you might be at an increased risk for seizures.
Before discontinuing the treatment you should discuss the consequences with your doctor.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Depalept may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Contact the doctor immediately if you experience the following side effects:
- Damage to the liver (hepatitis) or pancreas (pancreatitis), which may be severe and life-threatening. These effects can start abruptly with tiredness, loss of appetite, fatigue, somnolence, nausea, vomiting and intestinal pain.
- An allergic reaction which includes:
  - Sudden swelling of the face and/or neck that causes difficulty breathing and is life-threatening (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 (erythema multiforme), emergence of blisters with detachment of the skin (toxic epidermal necrolysis, Stevens-Johnson syndrome).

Additional possible side effects:
- Congenital malformations and physical and mental development disorders (see the section "Pregnancy, breastfeeding and fertility").

Additional side effects:
Very common side effects – side effects that occur in more than one out of ten users:
- Tremor
- Nausea

Common side effects - side effects that occur in 1-10 out of 100 users:
- At the beginning of treatment: vomiting, abdominal pain, diarrhea
- Weight gain
- Headaches
- Somnolence
- Seizures
- Memory impairment
- Confusion, aggressiveness, nervousness, attention disorders, hallucinations (seeing or hearing non-existing things)
- Extrapyramidal disorders (symptoms include: tremor, limb rigidity and difficulty walking)*
- Urinary incontinence
- Quick and involuntary eye movements
- Hearing impairment
- Gum problems, especially overgrowth of the gums (gingival hyperplasia)
- Pain and swelling in the mouth, ulcers in the mouth and a burning sensation in the mouth (stomatitis)
- Hair loss
- Irregular menstrual periods
- Bleeding
- Nausea or dizziness
- Nails and nail bed disorders
- Decrease in red blood cell count (anemia) and platelet count (thrombocytopenia)
- Low levels of sodium in the blood (hyponatremia, a symptom of improper secretion of antidiuretic hormone)

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
- Alertness impairment which may develop into a temporary coma, with remission after dose reduction or treatment cessation
- Difficulty in movement synchronization
- Reversible parkinsonism*
- Sensation of numbness/tingling in the skin (paresthesia)
- Hair problems (changes in the hair structure, color or growth)
- Rash or hives on the skin
- Hyperandrogenism (symptoms include excessive hairiness, especially in women, development of masculine features in a woman, acne)
- Decrease in body temperature (hypothermia)
- Swelling of the extremities (edema)
- Lack of menstrual period
- Worsening and increased frequency of convulsions. Onset of a different type of seizures
- Breathing difficulties and pain, due to inflammation of the protective membranes of the lungs (pleural effusion)
- Decrease in the numbers of all blood cells: white blood cells, red blood cells and platelets (pancytopenia), decrease in the number of white 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
- 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. Do not discontinue the treatment without consulting with the doctor first
- Impaired functioning of the ovaries (polycystic ovaries)
- 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 severe (rhabdomyolysis)
- Weight gain
- Kidney damage (kidney failure, tubulointerstitial nephritis, Fanconi syndrome)
- Increase in the size of red blood cells (macrocytosis), a significant decrease in white blood cell count (agranulocytosis)
- Decreased and irregular blood cell production
- Decrease in coagulation factors, abnormal coagulation test results (such as: increase in partial thromboplastin time and INR time)
- Decrease in the levels of vitamin B8 (biotin)/biotinidase
- Increased ammonium blood levels
- Double vision
- Dementia and cognitive disorders* that appear gradually and recede several weeks to several months after stopping treatment

Do not discontinue the treatment without consulting with the doctor first.
*Symptoms may include signs in brain imaging (atrophy).
Additional side effects in children:
Some side effects of valproate occur more frequently in children or are more severe compared to adults. These effects include liver damage, inflammation of the pancreas, aggressiveness, nervousness, attention disorders, behavior that is not within the norm, hyperactivity and learning disorders.
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:
https://sideeffects.health.gov.il/

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 refers to the last day of that month.
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 also contains:
Depalept syrup:
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, 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 glass bottle containing a cherry-red colored syrup.
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.
Marketing authorization holder and address: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi 83057, Israel.
Name and address of the manufacturer: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi 83057, Israel.
This leaflet was revised in 12/2022 in accordance with the Ministry of Health guidelines.
Registration numbers of the medicines in the national drug registry of the Ministry of Health:
Depalept syrup: 337222644
Depalept 200 mg enteric-coated tablets: 483023229
Depalept 500 mg enteric-coated tablets: 337122348

LFL 022 12/22