Patient Package insert in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed with a doctor's prescription only

Laif® 600 Film-Coated Tablets

NAME OF THE MEDICINE, ITS FORM AND STRENGTH:

Name of the medicine: Laif® 600

Form: Film-coated tablets.

Active ingredient and its quantity per dosage unit: Each film-coated tablet contains 612 mg of dry extract of St. John's Wort.

The plant St. John's Wort is also called *Hypericum perforatum*.

For a list of allergenic and inactive ingredients in the medicine - see section 6.

Read this leaflet carefully in its entirety before using the medicine.

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

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

The medicine is intended for adults and adolescents aged 12 years and above. The medicine is not intended for children under the age of 12 and infants.

Summary of vital information about the medicine:

- The medicine is intended to alleviate symptoms of mild to moderate depression, accompanied by anxiety, tension, restlessness or nervousness, depressed moods, changing moods, difficulties in falling asleep and difficulty in staying asleep for the entire night.
- The medicine is intended for adults and adolescents aged 12 years and above.
- This medicine is not intended for children and infants.
- The usual dosage, unless otherwise indicated by the doctor: one tablet a day, in the morning.
- Swallow the medicine with some water, during or after the meal. Do not chew. If you have difficulty in swallowing the tablet whole, the tablet may be halved along the score line marked on the tablet. Take the two halves one after the other. Do not take half a tablet as a single dose.

1) WHAT IS THE MEDICINE INTENDED FOR?

This medicine belongs to the group of antidepressants. The medicine is intended to alleviate symptoms of mild to moderate depression, accompanied by anxiety, tension, restlessness or nervousness, depressed moods, changing moods, difficulties in falling asleep and difficulty in staying asleep all night long.

The medicinal activity (also called "**Therapeutic group**") of the medicine is a natural herbal antidepressants.

2) BEFORE USING THE MEDICINE:

☒ Do not use the medicine:

- If you are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine. The active ingredient appears in section 1, and the additional ingredients are detailed in section 6.
- If you have developed a hypersensitive reaction to the sun as a result of taking the medicine.
- If you suffer or have suffered in the past from impaired function of the liver or the kidney.
- If you are taking one or more of the following medicines: medicines for the prevention of transplant rejection by the body (Ciclosporin, Oral Tacrolimus, Sirolimus), medicines for the treatment of AIDS disease (HIV) (Indinavir, Nevirapine), chemotherapy medicines (Imatinib, Irinotecan).
- If you are taking any other antidepressants.
- In children under the age of 12.

Special warnings regarding the use of the medicine:

- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Do not use this medicine for a prolonged period without consulting the doctor.
- Do not use this medicine if you have developed in the past a reaction of hypersensitivity to the sun as a result of taking the medicine or medicines containing the active ingredient, such as the plant St. John's Wort, *Hypericum perforatum* plant or Hypericins.
- Inform the attending doctor that you are taking this medicine if you are about to undergo a photodynamic diagnosis or treatment (a treatment with light).
- During the treatment with the medicine avoid intense exposure to UV radiation, such as visiting a solarium or tanning salons.
- If you are about to undergo surgery, inform the anesthesiologist that you are taking this medicine.
- Use of this medicine may increase or decrease the efficacy of other medicines. You must inform the doctor or pharmacist if you are taking one or more medicines listed in the following section: "If you are taking other medicines".

! If you are taking other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, inform the doctor or pharmacist if you are taking the following medicines:

- Anticoagulants and blood thinners (such as Warfarin, Phenprocoumon, Rivaroxaban), Digoxin, Midazolam, Simvastatin, Ivabradine, Verapamil. Tricyclic antidepressants (such as Amitriptyline, Nortriptyline). SSRI antidepressants (such as Paroxetine, Sertraline). Medicines for treating Parkinson's disease (such as Rasagiline).
- See additional list of medicines in section 2 ("**Do not use the medicine**"). Do not take the medicine if you are taking one or more of the following medicines: medicines for the prevention of transplant rejection by the body (Ciclosporin, Oral Tacrolimus, Sirolimus), medicines for the treatment of AIDS disease (HIV) (Indinavir, Nevirapine), chemotherapy medicines (Imatinib, Irinotecan).
- Using this medicine concomitantly with oral contraceptives may cause mild breakthrough bleeding (indicated by spotting) and thus impair the efficacy of the oral contraceptive. If you are taking oral contraceptives, use additional contraceptive methods during the time that you are using the medicine.

! Important information regarding some of the components of the medicine: The medicine contains lactose and may cause an allergic reaction in people sensitive to lactose.

Each tablet contains 64 mg of lactose monohydrate.

! Pregnancy and breastfeeding: If you are pregnant or breastfeeding, consult the doctor or pharmacist before using the medicine.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage for adults and adolescents 12 years and above is:

The usual dosage is one tablet a day, in the morning. Do not exceed the recommended dose.

Swallow the medicine with a little water, with or after a meal. Do not chew. If you have difficulty in swallowing the tablet whole, the tablet may be halved along the score line indicated on the tablet. Take the two halves one after the other. Do not take half a tablet as a single dose. This medicine is approved for use from the age of 12 years and above.

This medicine is not intended for children and infants.

Duration of treatment: Your doctor will determine the duration of treatment according to the state of your disease. Consult the attending doctor about the duration of the required treatment. Do not exceed the recommended dose nor duration of the recommended treatment without a doctor's instructions.

Since the effect of the medicine increases gradually, make sure to take the medicine on a regular basis. It is essential to take the medicine for 4 to 6 weeks in order to achieve a noticeable improvement in the symptoms of the disease. If you do not experience an improvement or bettering of your condition, or in the event that there is a worsening of your condition after 4 weeks of treatment with the medicine even though you took it according to the recommended instructions for use, consult the attending doctor about the continuation of treatment.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. In an event of an overdose, make sure to avoid overexposure to the sun or to UV radiation for a period of one to two weeks, because of the possibility of oversensitivity of the skin. Avoid sun exposure on exposed skin, make sure to wear appropriate clothing and to use a sunscreen cream with a high protection factor. In the event of an overdose, side effects associated with use of the medicine may be intensified.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult the doctor.

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor or pharmacist.

How can you contribute to the success of the treatment?

Complete the full course of treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS:

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using the medicine and refer to the doctor immediately if you feel or suffer from:

Hypersensitivity of the skin to the sun (photosensitivity) or to UV radiation (by visiting a solarium or tanning salons), sunburns. Overexposure to the sun, especially by people with very light skin can cause hypersensitivity to pain, cold or a burning sensation of the skin (Dysesthesia). These effects are rare following use of the medicine. See also "Special warnings regarding use of the medicine".

Side effects: The color of the urine may become a more intense yellow. This is due to the natural dye riboflavin added to the tablet coating and which is of no consequence.

Side effects that rarely occur (frequency between 1 out of every 1000-10,000 people using the medicine): Allergic skin reactions, stomach pains, abdominal discomfort, weakness, fatigue, restlessness.

If one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Driving and use of machinery: No studies regarding the effect of the active ingredient of the medicine on the ability to drive and use machines have been performed

5) HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage Conditions: Store at a temperature below 25°C. Protect from moisture. Store in the original package.

6) FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Croscarmellose Sodium, Eudragit® E100, Colloidal Anhydrous Silica, Lactose Monohydrate, Macrogol 4000, Magnesium Stearate, Maltodextrin, Riboflavin, Talc, Titanium Dioxide.

What the medicine looks like and the contents of the package: The medicine is an elliptic yellow tablet, with a score line in the middle. The tablets are packed in plastic blisters in carton boxes.

Package size: The medicine is supplied in carton packs containing plastic blister tray(s) with 20 tablets. The number of plastic trays in each carton pack may vary according to the package size. The number of tablets in each package is stated on the carton pack. Not all the pack sizes may be marketed.

Registration holder: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.

Manufacturer: Steigerwald Arzneimittelwerk GmbH, Germany (in cooperation with Klocke Pharma-Service GmbH and Klocke Verpackungs-Service GmbH, Germany).

The format of this leaflet was determined, checked and approved by the Ministry of Health in Mars 2015.

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