Patient package insert according to Pharmacists' Regulations (Preparations) - 1986

This medicine can be sold with a physician's prescription only

Ibufen® 600 - caplets

Each caplet of **Ibufen 600** contains: Ibuprofen at a dosage of 600 mg.

Inactive ingredients: see section 6 "Additional information and in section 2 "Important information" about some of the ingredients of this medicine". Read this entire leaflet carefully before using inhibitors

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

this medicine.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think that their illness is the with fatal outcome, have been reported with all allergy, as these may be the first signs of a very same as yours.

This medicine is intended for adults and adolescents above the age of 12.

1. What is the medicine intended for?

Ibufen 600 is an anti-inflammatory and an analgesic medicine for arthritis and osteoarthritis; for the relief of mild to moderate pain, such as: headache. toothache, menstrual pain, backache, muscle ache, Therapeutic group: Ibuprofen belongs to nonsteroidal anti-inflammatory drugs (NSAIDs) group.

2. Before using the medicine Do not use the medicine if:

 You are hypersensitive (allergic) to the active ingredient (ibuprofen), or to any of the other ingredients this medicine contains (see section 6)

You have suffered in the past from a hypersensitivity reaction (such as asthma attacks. swellings of the nasal mucous membrane or skin reactions) after taking aspirin or other NSAIDs.

You suffer from unexplained blood disorders.

You suffer or have suffered in the past from a gastrointestinal (GI) ulcer or bleeding (at least 2 distinct episodes of ulceration or bleeding). You have suffered in the past from GI bleeding

or perforation related to previous NSAID therapy. You suffer from brain haemorrhage or other active bleeding.

You suffer from severe liver or kidney impairment

 You suffer from severe congestive heart failure. · You are in the last three months of pregnancy.

Special warnings regarding the use of the medicine:

Consult the doctor or pharmacist before taking Ibufen 600.

Consult the doctor or medical staff if you have an infection - see section "Infections" below.

Children and adolescents

Do not take **Ibufen 600** under the age of 12, since the active ingredient content is too high. For this age group, there are other ibuprofen preparations containing lower dosage of the the recommended dose or duration of active ingredient.

Elderly patients

In elderly patients, side effects after taking before taking lbufen 600 if: NSAIDs are more frequent; especially bleeding You suffer or have suffered in the past from

and perforation in the stomach and intestines. which may possibly become life-threatening. An especially careful medical supervision is thus necessary in these patients.

Safety in the gastrointestinal tract

Try to avoid concomitant use of Ibufen 600 with other NSAIDs, including COX-2 selective

Side effects may be minimized by using the . Skin reactions lowest dose for the shortest possible duration Severe skin reactions have been reported in required to control symptoms.

ointestinal (GI) tract

NSAIDs. They have occurred at any time during severe skin reaction (see section 4). treatment, with or without warning symptoms or • Avoid taking Ibufen 600 during chickenpox a previous history of serious GI events.

The risk of GI bleeding, ulcer or perforation • Infections increases with increasing NSAID doses, in **Ibufen 600** may hide signs of infections such patients with a history of ulceration, especially as fever and pain. It is therefore possible that with complications of bleeding or perforation (see | Ibufen 600 may delay appropriate treatment of possible dose

The doctor will consider combination therapy infections related to chickenpox. If you take this with agents protecting the stomach lining (e.g. medicine while you have an infection and your misoprostol or proton pump inhibitors (PPI)) for symptoms of the infection persist or worsen, these patients, and also for patients requiring consult a doctor without delay. concomitant low dose aspirin (acetylsalicylic • lbufen 600 should only be used after the acid), or other medicines likely to increase the doctor carefully weighs the benefit-risk-ratio:

If you have a history of side effects in the GI tract, disorders (e.g. porphyria). particularly if you are elderly, you should report If you suffer from certain autoimmune any unusual abdominal symptoms (especially GI bleeding) particularly in the beginning of treatment. You should be careful if you receive concomitant • Special medical supervision is necessary: medication that can increase the risk of ulcers Directly after large operations. or bleeding, such as oral corticosteroids, In patients who suffer from allergies (e.g. skin anticoagulants such as warfarin, selective serotonin re-uptake inhibitors (SSRIs), which are used to treat depression, for example, or anti-platelet agents such as aspirin (see below

section "Drug interactions"). occurs.

NSAIDs should be given with caution to patients with a history of GI disease (ulcerative colitis. Crohn's disease) as these conditions may worsen • Ibuprofen, the active ingredient of Ibufen 600. (see section 4 "Side effects").

Cardiovascular effects

Anti-inflammatory medicines/painkillers like ibuprofen may be associated with a small increased risk of a heart attack or a stroke. especially if used in high doses. Do not exceed

treatment

You should consult the doctor or pharmacist

heart disease, including heart failure and angina (chest pain), have had a heart attack. bypass surgery, peripheral artery disease (circulatory disorders in the legs or feet caused by constricted or blocked arteries), or any kind of stroke (including mini stroke or transient ischaemic attack - TIA).

You suffer from high blood pressure, diabetes or high cholesterol levels or if there is a history of heart disorders or stroke in your family or if you are a smoker.

connection with ibuprofen treatment. Stop taking eeding, ulcers and perforation in the Ibufen 600 and consult the doctor immediately at the appearance of a skin rash, lesions of the

(varicella infection).

section 2 above) and in elderly patients. These infection, which may lead to an increased risk patients should start treatment with the lowest of complications. This has been observed in pneumonia caused by bacteria and bacterial skin

If you suffer from certain congenital blood disorders (systemic lupus erythematosus and

mixed connective tissue disease).

reactions to other medicines, asthma, hay membrane or chronic respiratory diseases that narrow the airways.

In patients with impaired kidney or liver function. You should stop taking Ibufen 600 if • Acute hypersensitivity reactions (e.g. anaphylactic gastrointestinal (GI) bleeding or ulceration shock) have been reported very rarely. Ibufen 600 hypersensitivity reaction signs. Adequate therapeutic measures have to be taken by the medical staff.

may temporarily inhibit platelet function (platelet aggregation). Patients with coagulation disorders should therefore be monitored closely by the doctor.

 In long-term therapy with Ibufen 600, liver function. kidney function and blood count should be checked

Inform the doctor or dentist about taking this medicine before operations.

 During prolonged use of painkillers, headaches may appear. They must not be treated by increasing the dose of the medicine. Consult the doctor if you suffer

the risk for renal failure (analgesic nephropathy).

or if you have problems becoming pregnant (see coagulation. Pregnancy, breastfeeding and fertility" section).

Drug interactions: other medicines, including non-prescription interaction between ibuprofen and sulfonylurea may affect or be affected by other medicines. concomitant therapy. Especially inform the doctor or pharmacist if you . Tacrolimus: there is an increased risk of nephrotoxicity are taking

inhibitors like captopril, beta-blockers like atenolol. treatment with zidovudine and ibuprofen. angiotensin II receptor antagonists like losartan). • Quinolone antibiotics (e.g. ciprofloxacin). is recommended to monitor blood levels of digoxin medicines.

· Diuretics or medicines to lower blood pressure. You should avoid drinking alcohol whilst taking Duration of treatment: Ibufen 600 may reduce the effect of these Ibufen 600.

• ACE inhibitors (for the treatment of heart failure and If you are pregnant or breastfeeding, think you. The duration of treatment will be determined by use of this medicine, consult the doctor or high blood pressure) - Ibufen 600 may reduce the may be pregnant or are planning to become the treating physician. effect of these medicines. Concomitant administration pregnant, consult a doctor before taking this Take the lowest effective dose for the shortest 4. Side effects may also increase the risk of sudden renal failure. medicine. Potassium-sparing diuretics - concomitant <u>Pregnancy</u> administration with Ibufen 600 may cause an Consult the doctor if you become pregnant while urgently if the symptoms (such as fever and pain)

increased potassium level in the blood fever), chronic swelling of the nasal mucous • Anti-inflammatory medicines and other before taking ibuprofen in the first and second Method of administration: analgesics of the NSAID group or glucocorticoids trimester of pregnancy.

increases the risk of GI ulcer or bleeding.

before or after administration of methotrexate healthcare professional if necessary. increased methotrexate concentration and to an complications for the mother and child. increase of its side effects

· Ciclosporin (medicine to prevent transplant The active ingredient ibuprofen and its too weak. rejection or for the treatment of rheumatism) – decomposition products pass into breast milk in If you have accidentally taken a higher dosage Possible side effects concomitant administration with certain NSAIDs low concentrations only. As adverse effects for If you took an overdose or if a child has accidently The following side effects depend mainly on the Very rare: severe general hypersensitivity increases the risk for the kidney-damaging effect the baby are not known, stopping breastfeeding is swallowed the medicine, refer immediately to a dosage and may vary individually; this has to be reactions. They may manifest in swelling of the *Vascular side effects: of ciclosporin. This effect cannot be ruled out for a usually not necessary during short-time treatment, doctor or to a hospital emergency room to get an taken into account. combination of ciclosporin with ibuprofen.

from frequent headaches despite taking Ibufen 600. • Medicinal products containing probenecid or Driving and using machines: Generally, habitual intake of painkillers, especially a sulfinpyrazone (for the treatment of gout) may combination of several analoesic active ingredients. delay ibuprofen excretion. This may lead to an increase of its side effects.

 Sulfonylurea (medicine to lower blood sugar If you are taking, or have recently taken between NSAIDs and this medicine. Although a safe grasp!

when ibuprofen is administered with tacrolimus. • Anticoagulants (medicines to thin the blood/to prevent • Zidovudine: there is evidence of an increased blood clotting, e.g. aspirin, warfarin, ticlopidine), risk of bleeding in the joints and haematoma in 3. How to use this medicine • Medicines to lower high blood pressure (e.g. ACE HIV positive haemophiliacs receiving concomitant. Always use this medicine according to the doctor's If you forgot to take the medicine at the set time,

Digoxin (for the treatment of heart diseases), • Mifepristone - NSAIDs should not be taken of administration of the medicine phenytoin (for the treatment of seizures) or 8-12 days after taking mifepristone, since these. The dosage and administration will be determined compensate for the missed dose. lithium (for the treatment of mental disorders) medicines may reduce the effect of mifepristone. by the doctor only. The usual recommended Continue with the treatment as recommended combination of Ibufen 600 with any of these Other medicines may affect or may be affected dosage is: medicines may increase their concentration in the by Ibufen 600. Therefore, you should consult One caplet, twice a day.

Use of the medicine and alcohol consumption: Do not exceed the recommended dose.

Pregnancy, breastfeeding and fertility:

taking Ibufen 600. You should consult the doctor continue or worsen (see section 2).

concomitant administration of lbufen 600 This medicine has a possible side effect of foetal empty stomach. If you have a sensitive stomach, The side effects are classified according the kidney impairment and low levels of amniotic you should take Ibufen 600 with food Anti-platelet agents and certain antidepressants fluid at about 20 weeks or later in pregnancy. It 'The caplet may be halved. Do not crush or Very common; appear in more than 1 user out must be discontinued at the first appearance of • Methotrexate - taking Ibufen 600 within 24 hours 20 weeks or later in pregnancy and to consult a medicine.

• Like other prostaglandin synthesis inhibitors, **Ibufen** • Anticoagulants like warfarin - NSAIDs may increase ability to drive and to operate machines. This is membranes (cyanosis) may also appear. 600 may make it more difficult to become pregnant. the anticoaquilant effect of these medicines. In all the more true in combination with alcohol. You The symptoms of metabolic acidosis can include the duration of treatment. Inform the doctor, if you plan to become pregnant concomitant use, it is recommended to monitor will not be able to respond to unexpected and nausea, stomach pain, vomiting (may be blood Oedema, high blood pressure and heart failure have Additional side effects: reaction. In this case, do not drive a car! Do not and shaky eye movement. At high doses, drowsiness, Medicinal products like Ibufen 600 may be levels) - clinical trials have shown interaction operate tools or machines! Do not work without chest pain, palpitations, loss of consciousness, associated with a slightly increased risk of a heart

medicines and nutritional supplements, tell has not been reported yet, surveillance of blood when riding a bicycle or playing near roads etc. breathing problems have been reported. GI bleeding, ulceration or perforation, even mucous membranes, blisters or other signs of an the doctor or pharmacist, since bluffen 600 glucose levels is recommended as a precaution in Important information about some of the There is no specific antidote. ingredients of this medicine:

This medicine contains less than 1 mmol sodium should consult the doctor. He/she will assess the - very rare. Early signs may be: fever, sore throat, Uncommon: visual disorders. (23 mg) per caplet that is to say essentially degree of poisoning and decide what measures superficial lesions in the mouth, flue-like symptoms, • Hearing system side effects: "sodium-free"

be determined according to their body weight.

In rheumatic disorders, the treatment with Ibufen medicine. Wear glasses if you need them. 600 may be necessary for a long period of time. If you have any further questions on the

duration necessary to relieve the symptoms. Like any medicine, the use of **Ibufen 600** may If you have an infection, consult the doctor

Swallow the caplet with water and not on an who will decide how to proceed.

(SSRIs) may increase the risk of GI bleeding. is recommended to avoid using NSAIDs at about chew the caplet to avoid the bitter taste of the of 10

(mainly for the treatment of neoplastic diseases, In the last trimester of pregnancy, you must not instructions. If you do not feel an adequate relief Rare: appear in 1-10 users out of 10,000. osoriasis and rheumatoid arthritis) may cause an take Ibufen 600 due to an increased risk of of pain, do not take a higher dosage without Very rare; appear in less than one user out of consulting the doctor. Consult the doctor if you 10 000 think the effect of Ibufen 600 is too strong or Unknown frequency: effects for which frequency

with ibuprofen. However, if a longer duration of opinion of the risk and advice on action to be taken. The most common side effects are GI in nature. Bring the medicine package with you.

treatment or higher doses are prescribed, early of the central nervous system such as headaches, 2 "Before using the medicine"). Nausea, vomiting, stopping of breastfeeding should be considered. dizziness, drowsiness and unconsciousness (in diarrhoea, flatulence, constipation, digestive children also myoclonic seizures) as well as stomach problems, abdominal pain, black stool, blood High doses of Ibufen 600 may cause adverse, ache nausea and vomiting. Furthermore, GI bleeding vomiting, ulcerative stomatitis, worsening of colitis reactions affecting the central nervous system such and liver or kidney disorders are possible. A drop and Crohn's disease (see section 2) have been may permanently harm the kidneys and increase accumulation of **Ibufen 600** in the body and to an as fatigue and dizziness. In individual cases, this in blood pressure, reduced respiration (respiratory reported following administration. Less frequently may influence the response time and impair the depression) and blue colour of skin and mucous incidences of gastritis have been reported. The risk

sudden events with a sufficiently quick and focused streaked), headache, ringing in the ears, confusion been reported in association with NSAIDs therapy. convulsions (mainly in children), weakness and attack or a stroke. As for children, they should be warned to be careful dizziness, blood in urine, cold body feeling, and Stop using the medicine and refer immediately

> On suspicion of an overdose of **Ibufen 600**, you thrombocytopenia, pancytopenia, agranulocytosis) • Eye side effects: should be taken as necessary

If you forgot to take the medicine

instructions. Check with the doctor or pharmacist do not take a double dose. Take the dose as if you are not sure about the dosage and method soon as you remember, unless it is almost time should be performed regularly. for the next dose. Never take a double dose to

by the doctor.

Even if there is an improvement in your health, blood. Blood level of lithium must be monitored. It the doctor before taking Ibufen 600 with other The dosage for children above the age of 12 should do not stop treatment without consulting the high blood pressure or with impaired kidney

> Do not take medicines in the dark! Check the label and the dose each time you take the pharmacist.

cause side effects in some users. Do not be kidney failure. alarmed while reading the list of side effects. You . Skin reactions may not suffer from any of them. If you notice any of the following side effects, consult the doctor.

following frequencies:

Common: appear in 1-10 users out of 100. Take Ibufen 600 according to the doctor's Uncommon: appear in 1-10 users out of 1,000.

has not yet been established

Possible symptoms of an overdose are disturbances particularly in the elderly, may occur (see section dangerous shock.

to a doctor if the following side effects appear: Abnormal blood formation (anaemia, leukopenia,

severe exhaustion, nosebleed and skin bleeding. In Very rare: ringing in the ears (tinnitus). these cases, do not take pain killers or fever-lowering medicines on your own.

During a long-term treatment, blood count test

 Severe pain in the upper stomach, blood or coffee ground coloured vomit, bloody and/or black stool. Kidney system disorders -

<u>Jncommon:</u> increased water retention in the tissue with oedema formation, especially in patients with function, nephrotic syndrome (water accumulation in the body - oedema, and excess protein in the urine), inflammatory kidney disorder (interstitial nephritis), which may be associated with an acute kidnev dysfunction.

Very rare: renal tissue lesions and increase in blood level of uric acid.

Reduced urination, accumulation of water in the body (oedema), and generally feeling unwell may be first signs of a kidney disorder or even

Very rare: severe skin reactions such as skin rash with reddening, peeling and blistering (e.g. Stevens-Johnson syndrome, toxic epidermal

Unknown frequency: a red, scaly widespread rash with bumps under the skin and blisters localized mainly on the skin folds, the torso, and the upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (see section 2).

Immune system disorders –

<u>Incommon:</u> hypersensitivity reactions with skin rash, itching of the skin and asthma attacks (possibly with drop in blood

pressure)

airways, breathing difficulties, fast heartbeat, hypertension) GI Ulcer, perforation or bleeding, sometimes fatal, wheezing, drop in blood pressure and even

At the appearance of any of these signs, which • Liver and gall-bladder side effects: may appear at the first dose of the medicine, immediate medical care is necessary

Refer to a doctor immediately at the appearance of GI bleeding depends mainly on the dose and or worsening of infection signs (e.g. reddening, swelling, overheating, pain, fever).

Very rare: palpitations, oedema (fluid retention), If a side effect appears, if any of the side effects heart failure, heart attack.

Nervous system side effects

Common: disturbances of the central nervous Side effects can be reported to the Ministry of system such as headache, dizziness, difficulty Health by clicking on the link sleeping, excitation, irritability or fatigue.

Gastrointestinal (GI) side effects:

Very common: Gl'complaints such as heartburn, odominal pain, nausea, vomiting, flatulence, diarrhoea, constipation and low GI bleeding. which may cause anaemia in exceptional cases. Common: GI ulcer (peptic ulcer), possibly with pleeding and perforation. Ulcerative stomatitis worsening of ulcerative colitis or of Crohn's

ncommon: gastritis Very rare: inflammation of the oesophagus and of the pancreas (pancreatitis), formation of membranous constrictions in the small and arge intestine.

Skin and subcutaneous tissue side effects:

Verv rare: hair loss. There have been exceptional cases of severe skin infection and soft tissue complications during a chickenpox infection.

Jnknown frequency: Skin sensitivity to light. severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)

· Infections and parasitic diseases:

Very rare: there is a correlation between systemic treatment with certain NSAIDs (including **Ibufen 600)** and worsening of infectious inflammations (e.g. development of necrotizing

Very rare: aseptic meningitis - the symptoms may Drug registration number at the national include strong headache, nausea, vomiting, fever, medicines registry of the Ministry of Health: stiff neck or disorientation, intolerance to bright 040 23 26009 00 light. Patients suffering from certain autoimmune lbufen 600 PB0421-06 disorders (such as systemic lupus erythematosus, mixed connective tissue disease) seem to be at

increased risk.

face, tongue and throat with constriction of the Very rare: high blood pressure (arterial

Very rare: liver dysfunction, liver damage especially in long-term therapy, liver failure acute inflammation of the liver (hepatitis). In long-term treatment, hepatic parameters should be checked regularly.

· Psychiatric side effects:

Very rare: psychotic reactions, depression

worsens or if you suffer from a side effect not listed in this leaflet, consult the doctor.

"דיווח על תופעות לוואי עקב טיפול תרופתי that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting, or via the following link: https://sideeffects.health.gov.il

5. How to store the medicine

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

Do not use this medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry

date refers to the last day of that month. Storage conditions: Store in a dry place. Do not

store above 25°C. Do not throw away any medicines via wastewater Ask your pharmacist how to throw away medicines you no longer use. These measures will help

protect the environment.

. Additional information In addition to the active ingredient this medicine also contains:

Microcrystalline cellulose, maize starch croscarmellose sodium, magnesium stearate hypromellose, carmellose sodium, silica colloida anhydrous, titanium dioxide (E171), stearic acid

talc, macrogol 400, carnauba wax. What the medicine looks like and what the package contains:

White caplets with a score line on both sides Approved package sizes: 15, 30 or 1000 caplets.

Not all pack sizes may be marketed Revised in July 2021 according to MOH

Manufacturer and registration holder: Dexcel® Ltd.

1 Dexcel St., Or Akiva 3060000, Israel