SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCTS

Adex® 200 / Ibupro 200
Adex® forte 400 / Ibupro forte 400 / Ibufen® 400
Adex® liqui-gels 200 / Ibupro liqui-gels 200
Adex® liqui-gels 400

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Adex 200 / Ibupro 200 / Adex liqui-gels 200 / Ibupro liqui-gels 200 contain 200 mg Ibuprofen
Adex forte 400 / Ibupro forte 400 / Ibufen 400 / Adex liqui-gels 400: contain 400 mg Ibuprofen

Each capsule of **Adex liqui-gels 200 / Ibupro liqui-gels 200** contains approximately 7 mg of sorbitol.
Each capsule of **Adex liqui-gels 400** contains approximately 11 mg of sorbitol.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Adex 200 / Ibupro 200: Pink, film-coated caplets, scored on one side.
The caplet can be divided into equal doses.

Adex forte 400 / Ibupro forte 400 / Ibufen 400: White, film-coated caplets, scored on both sides.
The caplet can be divided into equal doses.

Adex liqui-gels 200 / Ibupro liqui-gels 200: Blue, soft gelatine capsules imprinted with "200".

Adex liqui-gels 400: Blue, soft gelatine capsules imprinted with "400".

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adex 200 / Ibupro 200 / Adex forte 400 / Ibupro forte 400 / Ibufen 400:
For the treatment of pain associated with migraine.
For the relief of mild to moderate pain such as headache, toothache, primary dysmenorrhea, backache, muscular pain.
Anti - inflammatory and relieves pain in rheumatoid arthritis and osteoarthritis.
Adex 200 / Ibupro 200 are also indicated for the reduction of fever.

Adex liqui-gels 200 / Adex liqui-gels 400 / Ibupro liqui-gels 200:
For the treatment of pain associated with migraine.

Relief of mild to moderate pain such as headache, toothache, menstrual pain, backache, muscular pain, anti-inflammatory for rheumatic disease. Reduction of fever.

4.2 Posology and method of administration

For oral administration and short-term use only.
During short-term use, if symptoms persist or worsen the patient should be advised to consult a doctor.

Adults and children and adolescents between 12 and 18 years:
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4).
If in adults the product is required for more than 10 days, or if the symptoms worsen the patient should consult a doctor.
If in children and adolescents between 12 and 18 years this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Adults, Children and Adolescents between 12 and 18 years:

Take 200mg or 400mg with water, up to three times a day as required.

Leave at least four hours between doses.

Do not take more than 1200 mg in any 24 hour period.

Not for use by children under 12 years of age.

4.3 Contraindications

- Known hypersensitivity to the active substance, ibuprofen, or to any of the constituents listed in section 6.1, acetylsalicylic acid (aspirin) or other NSAIDs.
- History of gastrointestinal bleeding or perforation related to previous NSAIDs therapy.
- Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding or other gastrointestinal disorders).
- Patients who have previously shown hypersensitivity reactions (e.g. bronchospasm, asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, acetylsalicylic acid (aspirin) or other anti-inflammatory drugs (NSAIDs).
- Use in children under 12 years of age.
- Patients with severe hepatic failure, severe renal failure (see section 4.4).
- Severe heart failure (NYHA Class IV).
- During the third trimester of pregnancy (see section 4.6).

4.4 Special warnings and precautions for use

Masking of symptoms of underlying infections:
Ibuprofen can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When Ibuprofen is administered for fever or pain relief in relation to

infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to relieve symptoms.
If symptoms persist for more than 3 days, patients should be advised to consult their doctor.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal (see section 4.2).
Prolonged use of NSAIDs in the elderly is not recommended. Where prolonged therapy is required, patients should be reviewed regularly.

Other NSAIDs: The use of this product with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

Respiratory: Bronchospasm may be precipitated in patients suffering from, or with a previous history of, bronchial asthma or allergic disease.

Renal: Caution is required in patients with renal impairment since renal function may deteriorate (see sections 4.3 and 4.8).
The dose should be as low as possible and renal function should be monitored.

There is a risk of renal impairment in dehydrated children and adolescents.

Hepatic: Hepatic impairment (see section 4.8).

Gastrointestinal effects: NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as their condition may be exacerbated (see section 4.8 – undesirable effects).

Gastrointestinal (GI) bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without any warning symptoms or a previous history of serious GI events.

When GI bleeding or ulceration occurs in patients receiving Ibuprofen, the treatment should be withdrawn.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcers, particularly if complicated with haemorrhage or perforation (see section 4.3), and in the elderly. These patients should commence treatment on the lowest dose available.

Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk (see below and section 4.5).

Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin (see section 4.5).

Cardiovascular and cerebrovascular effects: Caution is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Clinical studies suggest that use of ibuprofen, particularly at high doses (2400mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤1200mg/day) is associated with an increased risk of arterial thrombotic events.

Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided.

Careful consideration should also be exercised before initiating longer-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.

Blood effects: As NSAIDs can interfere with platelet function, they should be used with caution in patients with idiopathic thrombocytopenic purpura (ITP), intracranial haemorrhage and bleeding diathesis.

Severe skin reactions: Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported rarely in association with the use of NSAIDs (see section 4.8). Patients appear to be at highest risk for these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. Ibuprofen should be discontinued at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity.

Exceptionally, varicella can be at the origin of serious cutaneous and soft tissue infectious complications. It is advisable to avoid use of ibuprofen in cases of varicella.

SLE and mixed connective tissue disease: Caution is advised in patients with systemic lupus erythematosus as well as those with mixed connective tissue disease due to increased risk of aseptic meningitis (see section 4.8).

Impaired female fertility: There is some evidence that drugs which inhibit cyclo-oxygenase / prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued.

The diagnosis of "Medication Overuse Headache" should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

Product specific special warnings:

Adex liqui-gels 200 / **Ibupro liqui-gels 200**/ **Adex liqui-gels 400** contain Sorbitol. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Adex 200 / **Adex forte 400** / **Ibufen 400** / **Ibupro 200** / **Ibupro forte 400** contain less than 1 mmol sodium (23 mg) per caplet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should be avoided in combination with:

Acetylsalicylic acid:

Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential increased adverse effects.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelets aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional use (see section 5.1).

Other NSAIDs including cyclooxygenase-2 selective inhibitors: avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects (see section 4.4).

Ibuprofen (like other NSAIDs) should be used with caution in combination with:

Anticoagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin (see section 4.4). It is considered unsafe to take NSAIDs in combination with warfarin or heparin unless under direct medical supervision.

Antihypertensives (ACE inhibitors and Angiotensin II Antagonists) and diuretics: NSAIDs may reduce the effect of diuretics and other antihypertensive drugs. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function) the co-administration of an ACE inhibitor or Angiotensin II antagonist and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. These interactions should be considered in patients taking ibuprofen concomitantly with ACE inhibitors or angiotensin II antagonists. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Corticosteroids: increased risk of gastrointestinal ulceration or bleeding (see section 4.4).

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see section 4.4).

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

Aminoglycosides: reduction in renal function in susceptible individuals, decreased elimination of aminoglycoside and increased plasma concentrations.

Lithium: decreased elimination of lithium.

Methotrexate: decreased elimination of methotrexate.

Ciclosporin: increased risk of nephrotoxicity with NSAIDs.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Probenecid: reduction in metabolism and elimination of NSAID and metabolites.

Oral hypoglycaemic agents: Inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increase risk of hypoglycaemia.

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with Zidovudine. There is evidence of an increased risk of haemarthrosis and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy.
In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

During the first and second trimester of pregnancy, ibuprofen should not be given unless clearly necessary. If ibuprofen is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

Rarely, taking NSAIDs after the 20th week of pregnancy may cause impaired renal function of the foetus, which may cause low levels of amniotic fluid (oligohydramnios).

The effects were observed after days to weeks of treatment. However, in rare cases, low levels of amniotic fluid were observed already after 48 hours of taking NSAIDs. In most cases, oligohydramnios passed with the treatment discontinuation.

Using NSAIDs after the 20th week of pregnancy should be limited. If it was decided that the benefit outweighs the risk for the foetus and the treatment with the medicine is essential after the 20th week of pregnancy, the lowest effective dose should be used for the shortest possible period.

Referring the patient to ultrasound scan should be considered, in order to estimate the amount of amniotic fluid when the treatment with therapeutic dosage of these medicines exceeding 5 days and stopping the treatment if low levels of amniotic fluid is detected.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose

- the foetus to:
  - cardiopulmonary toxicity (with premature closure of ductus arteriosus and pulmonary hypertension);
  - renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;
- the mother and the neonate, at the end of pregnancy to:
  - possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses;
  - inhibition of uterine contractions resulting in delayed or prolonged labour.

Increased formation of oedema in the mother could occur.

Consequently, ibuprofen is contraindicated during the third trimester of pregnancy.

Breast-feeding:

Ibuprofen and its metabolites can pass in very small concentrations (0.0008% of the maternal dose) into the breast milk and is unlikely to affect the breast-fed infant adversely. No harmful effects to infants are known, so it is not necessary to interrupt breast-feeding for short-term treatment with the recommended dose for mild to moderate pain and fever.

Fertility:

See section 4.4 regarding female fertility.

4.7 Effects on ability to drive and use machines

None expected at recommended dose and duration of therapy.

4.8 Undesirable effects

The list of the following adverse effects relates to those experienced with Ibuprofen at OTC doses (maximum 1200mg per day) in short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Adverse events which have been associated with ibuprofen are given below, tabulated by system organ class and frequency.

Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000) and not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Event
Blood and Lymphatic System Disorders	Very rare	Haematopoietic disorders[1]
Immune System Disorders	Uncommon Very rare	Hypersensitivity reactions consisting of urticaria and pruritus. Severe hypersensitivity reactions. Symptoms could be facial, tongue and throat swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock).[2]
Nervous System Disorders	Uncommon Very rare	Headache Aseptic meningitis[3]
Cardiac Disorders	Very rare	Cardiac failure and oedema[4]
Vascular Disorders	Very rare	Hypertension[4]
Respiratory, Thoracic and Mediastinal Disorders	Very rare	Respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea.
Gastrointestinal Disorders	Uncommon Rare Very rare Not Known	Abdominal pain, nausea anda dyspepsia[5] Diarrhoea, flatulence, constipation and vomiting Peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis[6], mouth ulceration and gastritis Exacerbation of colitis and Crohn's disease[7].
Hepatobiliary Disorders	Very rare	Liver disorders
Skin and Subcutaneous Tissue Disorders	Uncommon Very rare Not known	skin rash[2] Severe forms of skin reactions such as bullous reactions including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis can occur. Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP) Photosensitivity reactions
Renal and Urinary Disorders	Very rare	Acute renal failure[8]
Investigations	Very rare	Decreased haemoglobin levels, urea renal clearance decreased
Infections and infestations	Very rare	Exacerbation of infections related inflammation (e.g. development of necrotizing fasciitis), in exceptional cases severe skin infections and soft-tissue complications may occur during a varicella infection.

Description of Selected Adverse Reactions

[1] Examples include anaemia, leucopenia, thrombocytopenia, pancytopenia and agranulocytosis.
First signs are: fever, sore throat, superficial mouth ulcers and flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

[2] Hypersensitivity reactions have been reported. These may consist of (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract activity e.g. asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) various skin reactions, including rashes of various types, pruritus, urticaria, purpura, angioedema and more rarely exfoliative and bullous dermatoses (including toxic epidermal necrolysis, Stevens-Johnson Syndrome and erythema multiforme).

[3] The pathogenic mechanism of drug-induced aseptic meningitis is not fully understood. However, the available data on NSAID-related aseptic meningitis points to a hypersensitivity reaction (due to a temporal relationship with drug intake, and disappearance of symptoms after drug discontinuation). Of note, single cases of symptoms of aseptic meningitis (such as stiff neck, headache, nausea, vomiting, fever or disorientation) have been observed during treatment with ibuprofen, in patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease).

[4] clinical studies suggest that the use of ibuprofen (particularly at high doses 2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

[5] the adverse events observed most often are gastrointestinal in nature.

[6] sometime fatal, particularly in the elderly.

[7] see section 4.4

[8] especially in long-term use, associated with increased serum urea and oedema. Also includes papillary necrosis.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

In adults the dose response effect is less clear cut than in children where ingestion of more than 400mg/kg may cause symptoms. The half-life in overdose is 1.5-3 hours.

Symptoms: Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, abdominal pain, or more rarely diarrhoea. Tinnitus, headache, dizziness and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, nystagmus, blurred vision, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and loss of consciousness, hypotension and liver damage may occur. Exacerbation of asthma is possible in asthmatics. A dose in excess of 200 mg/kg carries a risk of causing toxicity.

Management: No specific antidote is available. Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within one hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: anti-inflammatory and anti-rheumatic products, non-steroids, propionic acid derivatives.

ATC Code: M01AE01

Ibuprofen is a propionic acid derivative, having analgesic, anti-inflammatory and antipyretic activity. The drug's therapeutic effects as a non-steroidal anti-inflammatory are thought to result from inhibitory activity on prostaglandin synthetase. Furthermore, ibuprofen reversibly inhibits platelet aggregation.
Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelets aggregation when they are dosed concomitantly. Some pharmacodynamics studies show that when single doses of ibuprofen 400mg were taken within 8 h before or within 30 min after immediate release acetylsalicylic acid dosing (81mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred.
Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 4.5).

Product specific pharmacodynamics properties:
Adex liqui-gels 200 / **Ibupro liqui-gels 200** / **Adex liqui-gels 400**:
Ibuprofen is dissolved in a hydrophilic solvent inside a gelatin shell. On ingestion, the gelatin shell disintegrates in the gastric juice releasing the solubilized ibuprofen for absorption.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. Ibuprofen diffuses into the synovial fluid. The excretion is rapid and complete via the kidneys.

Peak plasma concentration of ibuprofen occurs 1-2 hours after administration of ibuprofen.

Elimination half-life is approximately 2 hours.

Following hepatic metabolism (hydroxylation, carboxylation, conjugation), the pharmacologically inactive metabolites are completely eliminated, mainly renally (90%), but also with the bile. The elimination half-life in healthy individuals and those with liver and kidney diseases is 1.8 to 3.5 hours. Plasma-protein binding is about 99%.
No significant differences in pharmacokinetic profile are observed in the elderly.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adex 200 / **Ibupro 200:**

Microcrystalline cellulose, maize starch, croscarmellose sodium, magnesium stearate, hypromellose, carmellose sodium, silica colloidal anhydrous, talc, stearic acid, titanium dioxide E-171, erythrosine aluminium lake E-127, macrogol 400, carnauba wax, quinoline yellow aluminium lake E-104, brilliant blue FCF aluminium lake E-133.

Adex forte 400 / **Ibupro forte 400** / **Ibufen 400:**

Microcrystalline cellulose, maize starch, croscarmellose sodium, magnesium stearate, carmellose sodium, silica colloidal anhydrous, hypromellose, stearic acid, titanium dioxide E-171, talc, macrogol 400, carnauba wax.

Adex liqui-gels 200 / **Adex liqui-gels 400** / **Ibupro liqui-gels 200:**

Macrogol 600, purified water, potassium hydroxide, gelatin, sorbitol, sorbitan-1,4, maize starch, higher polyols, mannitol, patent blue E-131, titanium dioxide E-171.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Adex 200, Adex forte 400, Ibupro 200, Ibupro forte 400, Ibufen 400: Store in a dry place, not above 25°C.
Adex liqui-gels 200, Adex liqui-gels 400, Ibupro liqui-gels 200: Do not store above 25°C.

6.5 Nature and contents of container

Blister.

Pack sizes:

Adex 200: 10, 16, 20, 30, 40, 50, 100, 1000 caplets

Adex forte 400: 10, 20, 30, 40, 50, 100, 1000 caplets

Ibupro 200: 10, 16, 20, 30, 50, 100, 1000 caplets

Ibupro forte 400 / **Ibufen 400:** 10, 20, 30, 50, 100, 1000 caplets

Adex liqui-gels 200 / **Adex liqui-gels 400** / **Ibupro liqui-gels 200:** 2, 4, 8, 10, 16, 20, 24, 30, 32, 40, 50, 60, 70, 80 capsules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

Dexcel Ltd.
1 Dexcel Street, Or Akiva, 3060000, Israel

8. MARKETNG AUTHORISATION NUMBER(S)

Adex 200: 039712600700
Adex forte 400: 110282927000
Adex liqui-gels 200: 130183081600
Adex liqui-gels 400: 130193081700
Ibufen 400: 039702600800
Ibupro 200: 127983076200
Ibupro forte 400: 127973076300
Ibupro liqui-gels 200: 131183101700

Revised in August 2023 according to MOH guidelines.