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

The medicine is dispensed with a doctor's prescription only

Indovis capsules 25 mg

Each capsule contains indomethacin 25 mg
Inactive ingredients and allergens in the preparation – see the section "Important information about some ingredients of the medicine" and section 6.
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.

1. What is the medicine intended for?

Non-steroidal anti-inflammatory drug for treatment of rheumatism, osteoarthritis, spondylitis, hip osteoarthritis, acute problems in the skeletal muscles system and lower back pain.
Therapeutic class: Non-steroidal Anti-inflammatory Drugs (NSAIDs).

2. Before using the medicine:

☒ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (indomethacin) or any of the additional components the medicine contains (see section 6).
- You are sensitive to aspirin, ibuprofen or other NSAIDs, or you have developed signs of asthma (wheezing), runny nose, swelling of the face, lips, tongue or throat, or a rash with pale or red irregular raised patches with severe itching when taking these medicines.
- You are in the last three months of pregnancy or are breastfeeding.
- You are taking other NSAIDs (e.g. naproxen), including COX-2 inhibitors (e.g. celecoxib).
- You have angioneurotic edema (swelling of the face, lips, tongue or throat).
- You have or have had two or more episodes of gastric or intestinal ulcer, or bleeding in your stomach or intestines. Symptoms may include coffee ground vomit, black tarry stool and blood in your stool.
- You have severe liver, kidney or heart problems.
- You have a nasal obstruction (nasal polyps).

❗ Special warnings regarding the use of the medicine

- **Before using Indovis capsules, tell the doctor if:**
  - You have heart problems, have had a stroke or have risk factors for these conditions (e.g. high blood pressure, diabetes, high cholesterol or if you are a smoker).
  - You are elderly, have ulcerative colitis or Crohn's disease, as these increase the risk for stomach problems (e.g. ulcers or bleeding).
  - You have or have had any problems with your liver, heart or kidneys that may cause fluid retention.
  - You have asthma, a psychiatric disorder, epilepsy or Parkinson's disease (tremor, stiffness, shuffling).
  - You have blood clotting problems or are taking medicines for treatment of hypercoagulability.
  - You have an infection or are being treated for an infection, or you are receiving treatment with a live vaccine.
  - You have a connective tissue disorder, including systemic lupus erythematosus, which may cause joint pain, rash and fever.
  - You are trying to become pregnant or are undergoing investigation for infertility. Indomethacin may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.
  - You are taking nephrotoxic medicines, such as cisplatin or vancomycin.
  - You have an infection or sepsis.
  - You have extracellular volume depletion.
  - You have a peripheral arterial disease (a problem with blood circulation in the legs).
- If you are elderly or if you have a history of stomach ulcers, you have a higher risk for side effects, especially in the stomach. Your doctor will therefore prescribe the lowest dose that gives you relief. If you experience any symptoms in your stomach, you must tell your doctor about it.
- Taking this medicine may increase the risk for a stroke or a heart attack. The risk is increased particularly when it is taken for a prolonged period of time or in high doses. Do not exceed the recommended dosage, and do not take the medicine for longer than what your doctor advised.
- Taking analgesics for headaches frequently or for a prolonged period of time can make them worse.

❗ Children and adolescents
The medicine is not intended for children.
❗ Tests and follow-up

- Before any surgical procedure, including a surgical dental treatment, you should inform the doctor that you are using this preparation.
- You should inform the doctor about taking Indovis capsules if you are about to undergo laboratory tests. The medicine may affect the results of blood, liver and kidney tests.
- Regular blood and eye tests are recommended when this medicine is used for a prolonged period of time.

❗ Drug-drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell the doctor or the pharmacist.
Especially if you are taking:

- Other medicines for pain and swelling, including NSAIDs, aspirin, naproxen or COX-2 inhibitors (e.g. celecoxib) or diflunisal (for pain and inflammation).
- Medicines for lowering blood pressure.
- Anticoagulants or medicines for treatment of heart diseases, such as: captopril and lisinopril (ACE inhibitors), doxazosin and prazosin (alpha blockers), atenolol and propranolol (beta blockers), candesartan and losartan, hydralazine, nifedipine, pentoxifylline or digoxin.
- Diuretics, such as: furosemide, triamterene.
- Blood thinners, such as: coumarins, heparin, phenindione and warfarin.
- Methotrexate (mainly for treatment of malignant diseases, psoriasis and rheumatoid arthritis) and cyclophosphamide.
- Quinolone antibiotics (e.g., ciprofloxacin).
- Selective serotonin reuptake inhibitors (SSRIs) for treatment of depression.
- Phenytoin (for treatment of epilepsy).
- Diazepam (for anxiety, difficulty sleeping, alcohol withdrawal, seizures and muscle spasms).
- Steroids to treat swelling and allergies.
- Metformin or sulphonylureas, e.g. gliclazide for diabetes.
- Ciclosporin or tacrolimus or muromonab-CD3 to prevent transplant rejection.
- Haloperidol (an antipsychotic drug) or lithium for treatment of mental disorders.
- Zalcitabine, ritonavir or zidovudine for treatment of viral infections.
- Cardiac glycosides, such as: digoxin (for heart failure and arrhythmias).
- Pentoxifylline (for vascular disease and leg ulcers).
- Antacids (used to relieve heartburn).
- Baclofen, a muscle relaxant.
- Desmopressin for nighttime bed wetting.
- Mifepristone (for induction of abortion). Indovis should not be taken within 8-12 days of taking mifepristone.
- Probenecid for treatment of gout.
- Tiludronic acid for treatment of bone diseases.

❗ Use of the medicine and food
The medicine should be taken with or right after a meal.
❗ Pregnancy, breastfeeding and fertility
Do not use the medicine without consulting a doctor before starting the treatment if you are pregnant, might be pregnant, breastfeeding or planning to become pregnant. Indovis should not be taken during the last three months of pregnancy. Indovis may be taken during the first 6 months of pregnancy and while breastfeeding under medical supervision only.
This preparation has a potential side effect of kidney impairment in the fetus and oligohydramnios starting from week 20 of the pregnancy. It is recommended to avoid using preparations of the NSAID family starting from week 20 of the pregnancy, and consult a medical professional as necessary.
❗ Driving and operating machinery
In certain patients, this medicine may cause dizziness, drowsiness, tiredness, giddiness, vertigo or visual disturbances. If you feel these effects after using the preparation, you should avoid driving or operating dangerous machinery, and any activity that requires alertness.
❗ Important information about some ingredients of the medicine
This preparation contains lactose. If you have been told by the doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

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.
Do not exceed a dosage of 200 mg per day.
This medicine is not intended for children.
Do not exceed the recommended dose.
Do not open and scatter the content of the capsule. The medicine should be swallowed whole with food, milk or an antacid (a treatment for heartburn).
If you have accidentally taken a higher dosage, overdose effects may occur: nausea, vomiting, headache, abdominal pain and stomach bleeding, diarrhea, dizziness, drowsiness, fainting, disorientation, excitement, coma, numbness, convulsions, ringing or buzzing in the ears, renal failure, liver damage.
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 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 a doctor.
Follow the treatment as recommended by the doctor.
Do not take medicines in the dark! Check the label and the dose <u>every time</u> 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, use of Indovis 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.
Stop using the medicine and contact a doctor or proceed to a hospital immediately if you suffer from:

- Bloody or black stool, bloody vomit or coffee ground vomiting. These symptoms may indicate stomach or intestinal bleeding.
- An allergic reaction, signs may include: asthma, difficulty breathing or shortness of breath, swelling and irritation inside the nose, swelling of the eyelids, lips, tongue, throat, hands, feet or ankles.
- Digestive difficulties, heartburn, pain or other symptoms in the stomach area. These symptoms may indicate a gastric or intestinal ulcer.
- Aseptic meningitis, which may cause stiff neck, headache, vomiting, nausea, fever, disorientation, especially in patients who already have an autoimmune disease, such as systemic lupus erythematosus or mixed connective tissue disease.
- Inflammation, kidney damage or failure.
- Sugar, protein or blood in the urine.
- Altered liver function.
- Liver inflammation which may cause loss of appetite, abdominal discomfort, dark urine and yellowing of the skin and the whites of the eyes (jaundice).
- Change in the level of various types of blood cells, which may cause bleeding, bruising, fever, frequent infections and sore throat. Inform the doctor, who may refer you to blood tests.
- Nose bleeding, blood clotting in the body, blood count disturbances, reduction in blood cells production by the bone marrow.
- Ringing in the ears, hearing disorders, including deafness in rare cases.
- Inflammation of the optic nerve that may cause sudden loss of vision or pain during eye movement.
- Inflammation of the pancreas, which may cause severe abdominal pain and back pain.
- Vaginal bleeding.
- Red, flaky or peeling blisters on the skin, such as: severe rash including redness, peeling and swelling of the skin that resemble severe skin burns (toxic epidermal necrolysis), circular, irregular red patches on the skin of the hands and arms (erythema multiforme), severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome).

Additional side effects:
Effects on the heart and circulatory system:

- Flushing, fluid accumulation, high or low blood pressure.
- Chest pain, rapid or irregular heartbeat, palpitations.
- Heart failure, slightly increased risk for a stroke or a heart attack.

Effects on the blood:

- Decreased production of red blood cells (anemia), which may cause pallor, weakness or shortness of breath.
- High potassium levels (hyperkalemia) or sugar levels (hyperglycemia) in the blood.

Effects on the brain and the central nervous system:

- Depression, anxiety, disorientation, hallucinations, confusion, nervousness, lack of self-awareness.
- Dizziness or a sensation of spinning (vertigo).
- Speech disturbances.
- Numbness or tingling, involuntary movements, convulsions, aggravation of epilepsy or Parkinson's disease.
- Malaise, tiredness, weakness, difficulty sleeping, headache, dizziness, stupor, pre-fainting sensation, loss of consciousness, fluid build-up in the brain, coma.

Effects on the eyes:

- blurred vision, double vision.
- Pain in and around the eye.
- Deposits on the front surface of the eye (cornea), disturbances in the back part of the eye (retina).

Effects on the ears:

- Tinnitus or hearing disorders.

Effects on the stomach and intestines:

- Inflamed and painful mouth ulcers.
- Loss of appetite, sensation of nausea, diarrhea, flatulence, constipation, anorexia.
- Development or worsening of ulcerative colitis or Crohn's disease.
- Inflammation of the lining of the stomach or the small intestine, intestinal obstruction.

Effects on the skin:

- Worsening of psoriasis.
- Hair loss, sweating.
- Itching (pruritus), rash.
- Tender red lumps under the skin.
- Sensitivity to light (including sunbeds).

Effects on the muscles and bones:

- Muscle weakness, increased cartilage degeneration.

Effects on the breasts and reproductive system:

- Breast tenderness or enlargement, breast development in men.
- Vaginal bleeding.

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

- Store at a temperature lower than 25°C.
- Store in the original package.

6. Additional information:

In addition to the active ingredient, the medicine also contains:
Lactose, Cetyl Alcohol, Povidone, Titanium dioxide, Gelatin
What does the medicine look like and what are the contents of the package:
Opaque white capsules containing white, odorless powder. The capsules are supplied in a carton package containing 20, 30, 100, 500 or 1000 capsules in a blister package.
Not all package sizes may be marketed.
Manufacturer/license holder and address: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi.
This leaflet was revised in July 2022 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health: 132-45-25943

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