PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

Artofen® 200 mg
Artofen® 400 mg
Tablets

Composition
Each tablet contains:

Artofen® 200 mg Tablets	**Artofen® 400 mg Tablets**
Ibuprofen 200 mg	Ibuprofen 400 mg

For the list of inactive ingredients in the preparation, see section 6 – "Further Information".

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is dispensed without the need for a doctor's prescription and is intended for adults and children from the age of 12 years and up. Take this medicine properly. Consult a pharmacist if you need further information.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Artofen 200 mg
Intended for the relief of mild to moderate pains, such as: headache, toothaches, menstrual pains, back and muscle aches, anti-inflammatory in rheumatic diseases and for reduction of fever.

Artofen 400 mg
Intended for the treatment of rheumatoid arthritis and for osteoarthritis.
For the relief of mild to moderate pains and for the treatment of menstrual pains (first painful menstruation).

Therapeutic group
Non-steroidal anti-inflammatory drugs (NSAIDs).

2. BEFORE USING THIS MEDICINE

☒ Do not use this preparation if:
- you are pregnant.
- there is a known sensitivity to any of the ingredients of the medicine.
- you experienced in the past an allergic reaction when taking any pain reliever.
- you have just undergone or are due to undergo heart surgery.
- you are suffering, or have suffered in the past, from a peptic ulcer or from gastric bleeding, including due to use of medicines from the NSAID group.
- you are suffering from severe impairment in liver or kidney function, or from heart failure.
- Do not take concomitantly with other medicines from the NSAID group.

❗ Consult a doctor before starting treatment if you are suffering, or have suffered in the past, from:
- Stomach problems (e.g., abdominal pains, heartburn, etc.).
- Blood clotting problems.
- Hypertension.
- Heart and kidney diseases.
- Stroke or if you are in a risk group for stroke (e.g., high blood pressure or high cholesterol, diabetes or if you smoke).
- Impaired function of the respiratory system (e.g., asthma).
- Liver problems.
- Lupus erythematosus (a disease that affects the connective tissue and causes joint pains, changes in the skin and impaired function of other organs).
- Hay fever.
- Connective tissue diseases.
- If you are taking diuretics.
- If you are over the age of 60.
- If taking a medicine from this group or any other pain reliever caused severe side effects in the past.
- If you are pregnant or breastfeeding.

❗ Special warnings regarding use of this medicine
- Taking this medicine may cause gastric bleeding, especially if:
  - You are over the age of 60.
  - You have suffered in the past from a gastric ulcer or from gastric bleeding.
  - You are taking blood-thinning medicines, steroids, or other medicines from the NSAID group.
  - You consume more than 3 alcoholic beverages a day.
  - You are taking this medicine in high dosages or for a long period of time.
- Do not use this medicine frequently or for a prolonged period without consulting a doctor.
- Taking this preparation at a higher dosage than recommended or for a prolonged period may increase the risk of stroke or of heart attack and gastric bleeding.
- During prolonged treatment with this medicine, blood, urine, liver and kidney function and eye tests should be performed.
- This medicine may cause allergic reactions, such as: skin rash, itching, blistering of the skin, swelling of the face, shortness of breath, worsening of asthma, shock.
- Discontinue use and refer to a doctor if the fever lasts for more than 3 days or if the pains last for more than 10 days.
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.
- The anesthetist should be informed that you are taking this medicine if you are due to undergo surgery (including dental surgery), or laboratory tests, since the treatment may interfere with the test results.
- This medicine may cause a particular sensitivity upon exposure to the sun. Therefore, avoid exposure to the sun and be sure to have proper protection (long clothes, hat, sunscreens, etc.).

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines, herbal medicines, vitamins, and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or the pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with the medicine:
- Aspirin, salicylates and/or other anti-inflammatories.
- Anticoagulants (e.g., coumarin and its derivatives).
- Medicines for the heart (e.g., digoxin).
- Antihypertensives (e.g., beta blockers or captopril).
- Corticosteroids.
- Antidepressants (e.g., lithium and medicines from the SSRI group).
- Probenecid.
- Methotrexate (for cancer and psoriasis).
- Diuretics such as furosemide and thiazides.
- Zidovudine (for AIDS).
- Mifepristone (to induce miscarriage).
- Antibiotics from the quinolone and aminoglycoside group.
- Cyclosporine and tacrolimus (to prevent transplant rejection).

❗ Driving, operating machinery and activity requiring alertness
In certain people, this medicine may cause drowsiness, dizziness or blurred vision. If you experienced these effects after using the preparation, exercise caution when driving a car or when operating dangerous machinery. Children should be cautioned against riding bicycles or playing near roads, and the like.

❗ Use in pregnancy
Do not use this medicine if you are pregnant (see section 2).

❗ Use in breastfeeding
If you breastfeed, consult a doctor before using this medicine.

❗ Use in children
Use in children below the age of 12 years should be under medical supervision.

3. HOW SHOULD YOU USE THIS MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

Dosage
The usual dosage unless instructed otherwise by the doctor:
Artofen 200 mg:
Adults and children over the age of 12 years: 1-2 tablets, afterwards, and if necessary, 1-2 tablets every 4-6 hours.
Do not take more than 6 tablets within a 24-hour period.
Artofen 400 mg:
Adults and children over the age of 12 years: one tablet, 2-4 times a day.

Use in children below the age of 12 years should be under medical supervision.
Do not exceed the recommended dosage.
The lowest effective dose should be taken.
For relief of menstrual pains, start treatment as soon as the pains occur.

Use this medicine at specified time intervals. If you forgot to take this medicine at the specified time, take a dose as soon as you remember, but never take two doses together.

Directions for use
Do not chew, crush or halve the tablets! Swallow the medicine with water or milk, with or after a meal.

Tests and follow-up
During prolonged treatment with this medicine, blood, urine, liver and kidney function and eye tests should be performed.

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Artofen® 200 mg and Artofen® 400 mg 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 treatment and refer to a doctor immediately if the following effects occur:
(These effects occur at a very rare frequency of less than 1 in 10,000 patients)
- Peptic ulcer, symptoms may include: severe pains at the top of the stomach, bloody vomit (or fluid with coffee-colored grounds), bloody or black stools.
- Inflammation of the brain lining (meningitis) (such as stiff neck, headaches, nausea, vomiting, fever, achalasia and pains in the spine).
- Allergic reaction such as dizziness or fainting, tachycardia (rapid heart activity), facial edema, swelling of the tongue, throat, peeling or blistering of the skin.
- Worsening of asthma, shortness of breath, wheezing.

Other side effects
Uncommon effects at a frequency of less than 1 in 100 patients:
- Allergic reactions such as hives (skin disease), rash and irritation (or lupus erythematosus).
- Digestive system: abdominal pains, indigestion, heartburn, nausea.
- Nervous system: headache.

Effects at a frequency of less than 1 in 1,000 patients:
- Diarrhea, wind, constipation, nausea.

Effects at a frequency of less than 1 in 10,000 patients:
- Reduction in blood cells causing yellowing of the skin, fever, sore throat, mild sores in the mouth, flu-like symptoms, exhaustion or tiredness, bleeding from the nose or skin, development of bruises more easily.
- High blood pressure, heart failure or chest pains.
- Nervousness, hearing (ringing) or visual disturbances, dizziness.
- Liver problems (yellowing of the skin and eyes).
- Kidney problems (swelling of the ankles).
- Severe skin reactions: may include blistering of the skin.

Taking preparations such as ibuprofen may increase the risk of heart attack or stroke.

If a side effect occurred, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor immediately.

5. HOW SHOULD THIS MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from 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.
Do not store different medications in the same package.
Store in a dry place, below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Artofen 200 mg
Starch, sodium starch glycolate, silicon dioxide, povidone, magnesium stearate, hydroxypropylmethylcellulose, titanium dioxide.
Each 200 mg tablet contains 0.39-0.59 mg sodium.

Artofen 400 mg
Microcrystalline cellulose, sodium starch glycolate, silicon dioxide, povidone, magnesium stearate, hydroxypropylmethylcellulose, titanium dioxide, polyethylene glycol 400.
Each 400 mg tablet contains 0.95-1.43 mg sodium.

What the medicine looks like and the contents of the package:
Artofen 200 mg/Artofen 400 mg
White, convex tablets.

Manufacturer
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

License holder
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

This leaflet was checked and approved by the Ministry of Health on March 27, 2014.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
200 mg: 126.24.21692.00
400 mg: 058.46.21676.00

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