

**Patient package insert in accordance with the pharmacists'  
regulations (preparations) - 1986**

This medicine is sold without a doctor's prescription

## **Nurofen Cold and Flu, Tablets**

Active ingredients and their quantity:

Each tablet contains:

Ibuprofen 200 mg

Pseudoephedrine hydrochloride 30 mg

For list of inactive ingredients, see section 6.

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

You should take the product according to the instructions in the dosage section in this leaflet. Consult a pharmacist if you need further information. You should refer to the doctor in case the symptoms worsen or do not get better after 10 days.

### **1. What is the medicine intended for?**

For relief of cold and flu symptoms accompanied by pain, fever and nasal congestion.

#### **Therapeutic group:**

Ibuprofen - belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). These medicines provide relief by reducing pain, swelling and high temperature.

Pseudoephedrine - belongs to a group of drugs called vasoconstrictors which act on the blood vessels in the nose to relieve nasal congestion.

Nurofen Cold and Flu is intended for use in children older than 12 years and works in the following ways:

- Clears a blocked nose and sinuses
- Relieves pains, headache and high temperature
- Eases the discomfort of a sore throat

### **2. Before using the medicine**

#### **Do not use the medicine if:**

- you are hypersensitive (allergic) to ibuprofen, pseudoephedrine or any of the other ingredients contained in this medicine (see section 6).
- you have previously suffered from allergic reactions (such as: asthma, nose inflammation (rhinitis), subcutaneous swelling (angioedema) or hives (urticaria)) as a result of taking acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).
- you suffer or have previously suffered from bleeding / recurrent stomach ulcer (two or more significant events of perforation or proven bleeding).
- you have previously suffered from gastrointestinal bleeding or perforation related to previous treatment with medicines of the NSAID group.
- you suffer from severe heart disease, cardiovascular system disorders or severe hypertension.

- you suffer from severe heart, kidney or liver problems.
- you are in the last 3 months of pregnancy.
- you are under 12 years of age.
- you are taking Monoamine Oxidase Inhibitors (for depression, known as MAOIs) or have taken them in the last 14 days.

**Special warnings about the use of this medicine - before treatment with Nurofen Cold and Flu, tell your doctor if:**

- you suffer from asthma.
- you suffer from Systemic Lupus Erythematosus (SLE) - an illness affecting the immune system causing joint pain, skin changes and other problems.
- you suffer from liver or kidney problems, especially in dehydrated children and adolescents, as kidney problems may worsen.
- you suffer from high cholesterol or have previously had a heart attack or a stroke.
- you have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease).
- you are a smoker.
- you suffer from hyperthyroidism.
- you are diabetic, suffer from phaeochromocytoma (a small benign tumor in the internal part of the adrenal gland), glaucoma or prostate problems.
- you suffer from heart problems including heart failure, angina (chest pain), or have previously suffered from a heart attack, bypass surgery, peripheral vascular disease (poor feet circulation due to narrowed or blocked arteries), or any type of stroke [including a 'mini stroke' or a transient ischemic attack (TIA)].
- you suffer from high blood pressure, have a family history of heart disease or stroke.

**Other warnings:**

- Nurofen Cold and Flu belongs to a group of medicines, **which may impair fertility in women.** This is reversible on stopping use of the medicine. It is unlikely that Nurofen Cold and Flu, used occasionally, will affect your chances of becoming pregnant. However, tell your doctor before using this medicine if you have problems becoming pregnant.
- Anti-inflammatory/pain-killer medicines such as ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.
- Sudden abdominal pain or rectal bleeding may occur when taking Nurofen Cold and Flu due to inflammation of the colon (ischemic colitis). If you develop these symptoms - stop using the product and refer to your doctor or seek medical consultation immediately.

**Children and adolescents: The medicine is not intended for children under 12 years of age.**

**Drug interactions:**

**If you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements, please inform your doctor or pharmacist.** Nurofen Cold and Flu may affect or be affected by some other medicines such as:

- Anti-coagulants (for blood thinning/clot prevention such as aspirin/acetylsalicylic acid at a dosage less than 75 mg per day, warfarin, ticlopidine) as their effects may be stronger.
- This medicine should not be taken in combination with other non-steroidal anti-inflammatory drugs (NSAIDs) or with aspirin at a dosage that exceeds 75 mg per day.

- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan) and diuretics as Nurofen Cold and Flu may reduce the effects of these drugs.
- Corticosteroids, anti-platelet medicines, and selective serotonin reuptake inhibitors (SSRIs) as there is an increased risk of gastrointestinal bleeding.
- Cardiac glycosides used to stimulate the heart.
- Medicines for treating depression (lithium, selective serotonin uptake inhibitors) may affect or be affected by treatment with pseudoephedrine.
- Methotrexate, as Nurofen Cold and Flu may increase plasma levels of this medicine.
- Ciclosporin and tacrolimus, as there is an increased risk of kidney problems.
- This medicine should not be taken within 8-12 days of taking mifepristone (for termination of pregnancy).
- Zidovudine [for AIDS (HIV) treatment].
- Quinolone group antibiotics.
- When using monoamine oxidase inhibitors (MAOIs) (such as moclobemide) and/or reversible inhibitors of monoamine oxidase A (RIMAs), or within 14 days of stopping treatment with these medicines.
- Ergot alkaloids (ergotamine & methysergide).
- Other sympathomimetic medicines such as decongestants, amphetamine-like psychostimulants and appetite suppressants, as their effect may be increased by the pseudoephedrine contained in this medicine.
- Oxytocin, as there is a risk of increase in blood pressure.
- Anticholinergics, as they may affect the way that pseudoephedrine works.

**Some other medicines may also affect or be affected by treatment with Nurofen Cold and Flu. Always consult your doctor or pharmacist before taking Nurofen Cold and Flu with other medicines.**

### **Pregnancy, breastfeeding and fertility:**

Pregnancy: Avoid as much as possible using Nurofen Cold and Flu during the first 6 months of pregnancy. Do not use this medicine if you are in the last 3 months of pregnancy.

Breastfeeding: Do not use this medicine if you are breastfeeding.

Fertility: Nurofen Cold and Flu belongs to a group of medicines that may impair fertility in women. This condition is reversible on stopping use of the medicine. It is unlikely that occasional use of this medicine will affect the chance of becoming pregnant. However, if you are having difficulty becoming pregnant, consult a doctor before using the medicine.

### **3. How to use this medicine?**

You should check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with the product.

The usual recommended dosage is:

**Adults and children of 12 years and older:** 1 tablet every 4-6 hours, as long as the symptoms continue. If there is no response and there is no improvement in the pain or fever upon taking one tablet, 2 tablets can be taken. Do not take more than 6 tablets in 24 hours.

Take the lowest dose and for the shortest period of time necessary to relieve the symptoms.

**Do not exceed the recommended dose.**

**Duration of treatment:**

**Do not take the medicine for longer than 10 days** unless your doctor tells you to.

If symptoms persist or pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

**Manner of use:**

Swallow the medicine with water.

There is no information regarding crushing/halving/chewing.

**If you have taken an overdose or if a child has accidentally swallowed the medicine, always refer to a doctor or nearest hospital in order to get an opinion regarding the risk and to consult about the action to be taken.**

**If you have accidentally taken a higher dosage** the following symptoms may develop: nausea, abdominal pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and nystagmus.

At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body sensation, and breathing problems have been reported.

**If you forget to take the medicine** take according to the instructions of use written above, do not take more than recommended.

**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 the use of the medicine, consult the doctor or pharmacist.**

#### **4. Side effects**

As with any medicine, the use of Nurofen Cold and Flu may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

**Stop using the medicine and contact your doctor or seek medical attention immediately in case of:**

- **Signs indicating intestinal bleeding** such as:
  - Bright red stools, black tarry stools, vomiting blood or dark particles that look like coffee grounds
  
- **Signs indicating serious allergic reaction** such as:
  - Breathing difficulties
  - Dizziness or faster heartbeat
  - Severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (such as Stevens-Johnson syndrome)
  - Swelling of the face, tongue or throat
  
- **Signs of aseptic meningitis** with neck stiffness, headache, nausea, vomiting, fever or disorientation. Patients with autoimmune disorders (lupus, mixed connective tissue disease) have a higher chance to be affected.
  
- **A severe skin reaction known as DRESS syndrome** (Drug Reaction with Eosinophilia and Systemic Symptoms). Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase in the number of eosinophils (a type of white blood cells).

- **Sudden onset of fever, reddening of the skin, or many small pustules** (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) that may occur within the first two days of treatment with Nurofen Cold and Flu.
- **Inflammation of the colon** due to insufficient blood supply (ischemic colitis) (frequency not known).
- If you develop generalized erythema, associated with fever and pustules.

**Stop using the medicine and tell your doctor if you experience the following uncommon side effects:**

- Indigestion, heartburn or nausea.
- Pains in upper abdomen or other abnormal abdominal problems.
- Hallucinations, restlessness or sleep disorders.

**Tell your doctor if you suffer from any of the following side effects, if they become worse or if you notice any effects not mentioned:**

- **Uncommon side effects:**
  - Allergic reactions, such as skin rashes (urticaria), itching, peeling of the skin
  - Headaches, tremors
- **Rare side effects:**
  - Flatulence (wind), diarrhoea, constipation and vomiting
- **Very rare side effects:**
  - Blood disorder leading to unexplained or unusual bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion.
  - Drop in blood pressure or irregular heartbeat.
  - Stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation mouth mucosa with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis).
  - Liver and kidney problems, characterized by yellowing of the skin or eyes; swelling in hands, legs, ankles or feet; dark-coloured or bloody urine; pale, bloody or tar like stools; fatigue; shortness of breath; decreased appetite; or tendency to bruise easily.
- **Side effects with unknown frequency (effects for which the frequency cannot be determined from available data):**
  - Worsening of asthma or bronchospasm.
  - Swelling (oedema), high blood pressure, heart failure or heart attack, chest pain.
  - Worsening of colon inflammation (colitis) and Crohn's disease or dry mouth.
  - Decreased appetite, anxiety.
  - Excessive sweating, muscle weakness, difficulty in urinating, thirst.

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

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעת לוואי עקב טיפול" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://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 reach and sight of children and/or infants, 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) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.

In any case of doubt, consult the pharmacist who dispensed you the medicine. Do not store different medicines in the same package.

### **6. Additional information**

#### **In addition to the active ingredients, the medicine also contains:**

Calcium phosphate ,Croscarmellose sodium ,Microcrystalline cellulose, Povidone, Hypromellose, Opaspray yellow M-1 F-6168 (solids) or Mastercote yellow FA 0156 (solids), Magnesium stearate, Talc, Opacode Monogramming ink S-1-277001 Black, Isopropyl alcohol, Purified water, Industrial methylated spirit.

Each tablet contains: 3 mg sodium.

#### **What the medicine looks like and contents of the pack:**

Yellow tablet. The mark 'N' is printed on the tablet in black.

Each pack contains 24 tablets packed in a blister.

#### **Registration holder and address:**

Reckitt Benckiser (Near East) Ltd., 6 Hanagar St., Hod Hasharon, 4527704.

#### **Manufacturer and address:**

Reckitt Benckiser Healthcare International Ltd., Nottingham, UK.

**Revised in May 2020.**

**Drug registration number at the national medicines registry of the Ministry of Health:** 122 56 29971 00

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