SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Cold and Flu

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	Quantity
Ibuprofen	200mg
Pseudoephedrine Hydrochloride	30mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A yellow, round, biconvex film-coated tablet with an identifying logo in black.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For short-term use only.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 10 days.

Posology

Adults and children 12 years of age and over:
Take 1 tablet every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 tablet, 2 tablets may be used.
Do not use more than 6 tablets in any 24-hour period unless directed by a doctor.

Method of administration:
For oral administration with water.

Paediatric population: Nurofen Cold and Flu is not indicated for children under 12 years old.

4.3 Contraindications

Hypersensitivity to ibuprofen, pseudoephedrine or any of the excipients in the product.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs.

Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Severe coronary heart disease and cardiovascular disorders. Severe hypertension.

Severe heart failure, renal failure or hepatic failure (see section 4.4)

Last trimester of pregnancy (see section 4.6)

Not to be used in children under the age of 12 years.

Monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping treatment (see section 4.5).

4.4 Special warnings and precautions for use

Undesirable effects may be minimised by using the lowest effective dose for the shortest possible duration necessary to control symptoms (see GI and cardiovascular risks below).

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

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

Other NSAIDs:
The use of Nurofen Cold & Flu with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

SLE and mixed connective tissue disease:
Systemic lupus erythematosus and mixed connective tissue disease – increased

risk of aseptic meningitis (see section 4.8).

Renal:
Moderate to severe renal impairment as renal function may further deteriorate, especially in dehydrated children and adolescents. (see sections 4.3 and 4.8)
Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen products over long periods at high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose.

Hepatic:
Hepatic dysfunction (see sections 4.3 and 4.8)

Cerebrovascular effects:
Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of occlusive vascular disease, hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in associated with NSAID therapy.

Clinical trial and epidemiological data suggest that the use of ibuprofen, particularly at high doses (2400mg daily) and in long-term treatment 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 daily) is associated with an increased risk of myocardial infarction.

Impaired female fertility:
There is limited 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.

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

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

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

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).

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

Ischaemic colitis
Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other systems or ischaemic colitis develop.

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 with the first month of treatment. Nurofen Cold & Flu should be discontinued at the first appearance of a skin rash, mucosal lesions, or any other signs of hypersensitivity.

Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with ibuprofen and pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of Nurofen Cold & Flu should be discontinued and appropriate measures taken if needed.

Masking of symptoms of underlying infections:
Nurofen Cold and Flu 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 Nurofen Cold and Flu 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.

To be used with caution in patients with cardiovascular disease, tachycardia, hypertension, angina pectoris, hyperthyroidism, diabetes, phaeochromocytoma, closed angle glaucoma or elevated intraocular pressure, prostatic enlargement, hyperexcitability.

To be used with caution in combination with antihypertensives including adrenergic neurone blockers & Beta blockers (see section 4.5). The effects of a single dose on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment.

To be used with caution with other sympathomimetic agents such as decongestants, appetite suppressants and amphetamine-like psycho-stimulants (see section 4.5).

If hallucinations, restlessness, or sleep disturbances are experienced whilst taking the product, use of the product should be discontinued.

Ischaemic optic neuropathy
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Excipients
∗ This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Speak to a pharmacist or your doctor before taking if you:

- Have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems
- Are a smoker
- Are pregnant

If symptoms persist, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen (like other NSAIDs) should be avoided in combination with:
Acetylsalicylic Acid (Aspirin): Unless low-dose *Acetylsalicylic Acid (*aspirin) (not above 75mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions (see section 4.4).

Experimental data suggest that ibuprofen may inhibit the effect of low dose *Acetylsalicylic Acid (*aspirin) on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen 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 should be used with caution in combination with:
Anticoagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin (see section 4.4).

Antihypertensives and diuretics: NSAIDS and pseudoephedrine may diminish the effects of these drugs. 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 glycoside levels.

Sympathomimetics such as pseudoephedrine may increase risk of dysrhythmias.

Lithium: There is evidence for potential increases in plasma levels of lithium.

Methotrexate: There is a potential for an increase in plasma methotrexate.

Ciclosporin: Increased risk of nephrotoxicity.

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

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

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses 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.

Monoamine oxidase inhibitors (MAOIs) and/or Reversible inhibitors of monoamine oxidase A (RIMAs): should not be given to patients receiving MAOI therapy or within 14 days of stopping treatment: increased risk of hypertensive crisis.

Ergot alkaloids (ergotamine & methysergide): increased risk of ergotism.

Other sympathomimetic agents such as decongestants, amphetamine-like psychostimulants and appetite suppressants: pseudoephedrine may potentiate their effects. Risk of hypertension (see section 4.3)

Oxytocin: risk of hypertension.

Anticholinergics: the effect of pseudoephedrine may be diminished/enhanced by tricyclic antidepressants.

Guanethidine, reserpine and methyldopa: the effect of pseudoephedrine may be diminished.

Moclobemide: risk of hypertensive crisis

4.6 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 embryofoetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
From the 20th week of pregnancy onward, Nurofen use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation, therefore during the first and second trimester of pregnancy, Nurofen should not be given unless clearly necessary. If Nurofen 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. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to Nurofen for several days from gestational week 20 onward. Nurofen should be discontinued if oligohydramnios or ductus arteriosus constriction are found.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
cardiopulmonary toxicity (premature constriction/closure of the ductus arteriosus and pulmonary hypertension);
renal dysfunction (see above); which may progress to renal failure with oligohydroamniosis;
the mother and the neonate, at the end of the 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.
Consequently, Nurofen is contraindicated during the third trimester of pregnancy.
Breast feeding:
In limited studies, ibuprofen appears in the breast milk in very low concentrations and is unlikely to affect the breast-fed infant adversely.

Fertility:
See section 4.4 regarding female fertility.

4.7 Effects on ability to drive and use machines

None expected at recommended doses and duration of therapy.

4.8 Undesirable effects

The most commonly observed adverse events are with ibuprofen are gastrointestinal in nature.

The following list of adverse effects relates to those experienced with ibuprofen at OTC doses (maximum 1200mg per day) and sympathomimetics including pseudoephedrine for 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 and sympathomimetics including pseudoephedrine are given below, listed by system organ class and frequency. Frequencies are defined as: Very common (≥1/10), Common (≥1/100 and <1/10), Uncommon (≥1/1000 and <1/100), Rare (≥1/10,000 and <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	Hypersensitivity with urticaria and pruritus[2]
	Very rare	Severe hypersensitivity reactions including facial, tongue and throat swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock)[2]
Psychiatric Disorders	Not known	Insomnia, anxiety, restlessness, agitation, hallucination.
Nervous System Disorders	Uncommon	Headache, tremor
	Very rare	Aseptic meningitis[3], Muscular weakness
Cardiac Disorders	Not known	Cardiac failure and oedema[4], tachycardia, arrhythmia, palpitations.
Vascular Disorders	Not known	Hypertension[4]
Respiratory, Thoracic and Mediastinal Disorders	Not known	Respiratory tract reactivity including exacerbation of asthma, bronchospasm or dyspnoea[2].
Gastrointestinal Disorders	Uncommon	Abdominal pain, nausea and dyspepsia[5]

	Rare	Diarrhoea, flatulence, constipation and vomiting
	Very rare	Peptic ulcers, gastrointestinal perforation or gastrointestinal haemorrhage, melaena, haematemesis[6]. Mouth ulceration and gastritis.
	Not known	Dry mouth, exacerbation of colitis and Crohn's disease[7], ischaemic colitis.
Hepatobiliary Disorders	Very rare	Liver disorders
Skin and Subcutaneous Tissue Disorders	Not known	Hyperhidrosis Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Severe skin reactions, including acute generalized exanthematous pustulosis (AGEP) Photosensitivity reactions
	Uncommon	Skin rashes[2]
	Very rare	Bullous reactions, including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis[2]
Musculoskeletal and connective tissue disorders	Not known	Muscular weakness
Metabolism and Nutrition Disorders	Not known Not known	Decreased Appetite Hypokalaemia[9]
Renal and Urinary Disorders	Very rare	Acute renal failure[8]
	Not known	Urinary retention
	Not known	Ureteric colic, dysuria
	Not known	Renal tubular acidosis[9]
General and Administration Site Conditions	Not known	Chest pain, irritability, thirst,
Metabolism and Nutrition Disorders	Not known	Decreased Appetite
Investigations	Very rare	Haemoglobin decreased
Eye disorders	Not known	Ischaemic optic neuropathy

Description of Selected Adverse Reactions:

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

[2] Hypersensitivity reactions: These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity including asthma, aggravated asthma, bronchospasm and dyspnoea, or

(c) various skin reactions, including pruritis, urticaria, purpura, angioedema and, more rarely, severe forms of skin reactions such as exfoliative and bullous dermatoses (including toxic epidermal necrolysis can occur, Stevens-Johnson Syndrome and erythema multiforme).

[3] The pathogenic mechanism of drug-induced aseptic meningitis is not fully understood. However, the available data suggest that NSAID-related meningitis develops in individuals rendered susceptible by an underlying autoimmune disorder who were previously sensitized or had a natural immunity to the drug. 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 and mixed connective tissue disease).

[4] Clinical trial and epidemiological data suggest that use of ibuprofen (particularly at high doses 2400mg daily) and in long-term treatment 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] Sometimes fatal, particularly in elderly.

[7] See section 4.4.

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

[9] Renal tubular acidosis and hypokalaemia have been reported in the post-marketing setting typically following prolonged use of the ibuprofen component at higher than recommended doses

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 children ingestion of more than 400 mg/kg ibuprofen may cause symptoms. In adults the dose response effect is less clear cut. 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, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, 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 liver damage may occur. Exacerbation of asthma is possible in asthmatics.

As with other sympathomimetics, Pseudoephedrine overdose may cause symptoms of central nervous system and cardiovascular stimulation, including:
Irritability, restlessness, tremor, palpitations, convulsions, urinary retention, hypertension, tachycardia and cardiac arrhythmias.

Difficulty in micturition, nausea, vomiting may also occur in Pseudoephedrine overdose.

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 liver damage may occur. Prolonged use at higher than recommended doses may result in severe hypokalaemia and renal tubular acidosis. Symptoms may include reduced level of consciousness and generalised weakness (see section 4.4 and section 4.8).

Management
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 1 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.

A rapidly-acting alpha blocker, such as phentolamine, may be given to reverse alpha1-mediated effects such as hypertension, while a beta blocker may be given for beta1-mediated effects such as cardiac arrhythmias. In severe hypertension, rapidly-acting vasodilators such as glyceryl trinitrate have also been used.

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Anti-inflammatory and antirheumatic products, propionic acid derivatives. Ibuprofen combinations. **ATC Code:** M01AE51

Ibuprofen is a propionic acid derivative, having analgesic, anti-pyretic and anti-inflammatory activity. The drug's therapeutic effects as a non-steroidal anti-inflammatory drug are thought to result from inhibitory activity on

prostaglandin synthesis. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose aspirin (acetylsalicylic acid) on platelet aggregation when they are dosed concomitantly. Some pharmacodynamics studies show that when single doses of ibuprofen 400mg were taken with 8 h before or within 30 min after immediate release aspirin (acetylsalicylic acid) dosing (81mg), a decreased effect of ASA (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 relevant effect is considered to be likely for occasional use (see section 4.5).

Pseudoephedrine hydrochloride is used as a nasal and bronchial decongestant which acts by vasoconstriction to reduce oedema and nasal swelling. It is a stereoisomer of Ephedrine and has a similar action. It is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha- and beta-adrenergic activities and has stimulating effects on the central nervous system. It has a more prolonged, though less potent action than adrenaline. However, pseudoephedrine has been stated to have less pressor activity and central nervous system effects than ephedrine.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed from the gastrointestinal tract, peak serum concentrations occurring 1-2 hours after administration. The elimination half-life is approximately two hours.

Ibuprofen is metabolised in the liver to two major inactive metabolites and these together with unchanged ibuprofen are excreted by the kidney either as such or as conjugates. Excretion by the kidney is both rapid and complete.

Ibuprofen is extensively bound to plasma proteins.

Pseudoephedrine is absorbed from the gastrointestinal tract and is largely excreted in the urine unchanged, together with small amounts of a hepatic metabolite. It has an elimination half-life of several hours, which may be reduced by acidifying the urine.

5.3 Preclinical safety data

No data is available which is of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium phosphate, Croscarmellose sodium, Microcrystalline cellulose, povidone, Hypromellose, Opaspray Yellow M-1F-6168 or Mastercote Yellow FA 0156, Magnesium stearate, Talc, Opacode Monogramming ink S-1-277001 Black,

Isopropyl alcohol, Purified water, Industrial methylated spirit.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and contents of container

A strip pack consisting of a blister tray of white pigmented PVC/PVDC laminate heat-sealed to aluminium foil containing 12 tablets. Two trays packed in a cardboard carton (24 tablets) or Four trays packed in a cardboard carton (48 tablets).

6.6 Special precautions for disposal

Not applicable.

7 MANUFACTURER

Reckitt Benckiser Healthcare International LTD.
Nottingham NG2 3AA
England

8 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser (Near East) LTD.
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4527704

9 MARKETING AUTHORISATION NUMBER

122-56-29971-00

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