

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Care Cold & Flu Relief 200mg/5mg Film Coated Tablets

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each film-coated tablet contains the active substances:

200.0 mg Ibuprofen

5.0 mg Phenylephrine hydrochloride

For the full list of excipients, see Section 6.1.

### **3 PHARMACEUTICAL FORM**

White, round, biconvex film coated tablet with a score line on one side.

The score line is not intended for breaking the tablet.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For the relief of symptoms of cold and flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses.

#### **4.2 Posology and method of administration**

For oral administration and short-term use only.

Adults, the elderly and children over 12 years:

The lowest effective dose should be used for the shortest duration necessary to relieve/control symptoms and minimise undesirable effects (see section 4.4). The patient should consult a doctor if symptoms persist or worsen, or if the medicinal product is required for more than 10 days.

Two tablets every 8 hours. Leave at least 4 hours between doses and do not exceed six tablets in any 24 hour period.

Children:

Not to be given to children under 12 years.

### 4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Hypertension and severe coronary heart disease.
- Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes or proven ulceration or bleeding).
- History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
- Severe heart failure (NYHA Class IV), renal failure or hepatic failure (see section 4.4).
- Last trimester of pregnancy.
- Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors (see section 4.5).
- Hyperthyroidism.
- Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.
- Avoid in patients with prostatic enlargement

### 4.4 Special warnings and precautions for use

#### Ibuprofen

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

#### Elderly

The elderly are at increased risk of consequence 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 this medicinal product with concomitant NSAIDs, including cyclo-oxygenase-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

Renal impairment as renal function may further deteriorate (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).

#### Cardiovascular and cerebrovascular effects

Caution (discussion with doctor or pharmacist) 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 a high dose (2400 mg/day) 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.  $\leq 1200$  mg daily) 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 long-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.

Cases of Kounis syndrome have been reported in patients treated with Ibuprofen. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction-associated with constriction of coronary arteries and potentially leading to 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 on 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 in the elderly. These patients should commence treatment on the lowest dose available.

Patients with a history of GI toxicity, particularly the 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-platelets agents such as acetylsalicylic acid (see section 4.5).

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

#### Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome), and acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen (see section 4.8). Most of these reactions occurred within the first month.

If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate).

Masking of symptoms of underlying infections:

Care Cold & Flu Relief 200mg/5mg Film Coated Tablets 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 this medicine 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.

The label will include:

Read the enclosed leaflet before taking this product.

Do not take if you:

- Have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding.
- Are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers.
- Are taking other NSAID painkillers, or aspirin with a daily dose above 75 mg.

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 or worsen, consult your doctor.

Phenylephrine

Phenylephrine should be used with care in patients with cardiovascular disease, diabetes mellitus, closed angle glaucoma and hypertension.

Sodium content

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

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Ibuprofen

*Ibuprofen should not be used in combination with:*

Acetylsalicylic acid

Unless low-dose acetylsalicylic acid (not above 75 mg daily) has been advised by a doctor, concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects (see section 4.4).

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these ex-vivo 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 the occasional ibuprofen use (see section 5.1).

#### Other NSAIDs including cyclo-oxygenase-2 selective inhibitors

Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse reactions (see section 4.4).

*Ibuprofen should be used with caution in combination with:*

#### Anti-coagulants

NSAIDs may enhance the effects of anticoagulants such as warfarin (see Section 4.4).

#### Antihypertensives and diuretics

NSAIDs may diminish the effect of these drugs and may cause hyperkalaemia in patients under these treatments. Diuretics can increase the risk of nephrotoxicity.

#### 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.

#### Lithium

There is evidence for potential increase in plasma levels of lithium.

#### Methotrexate

There is 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 effect 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.

#### Phenylephrine

##### Sympathomimetics, vasodilators and beta-blockers

Phenylephrine may adversely interact with other sympathomimetics, vasodilators and beta-blockers.

##### Monoamine oxidase inhibitors (MAOIs)

Phenylephrine is not recommended for patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors (MAOIs).

## **4.6 Fertility, pregnancy and lactation**

#### Ibuprofen

Whilst no teratogenic effects have been demonstrated with ibuprofen in animal experiments, the use of this medicinal product should, if possible, be avoided during the first six months of pregnancy.

From the 20<sup>th</sup> week of pregnancy onward, Care Cold & Flu Relief 200mg/5mg Film Coated Tablets 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, Care Cold & Flu Relief 200mg/5mg Film Coated Tablets should not be given unless clearly necessary. If Care Cold & Flu Relief 200mg/5mg Film Coated Tablets 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 Care Cold & Flu Relief 200mg/5mg Film Coated Tablets for several days from gestational week 20 onward. Care Cold & Flu Relief 200mg/5mg Film Coated Tablets should be discontinued if oligohydramnios or ductus arteriosus constriction are found.

During the third trimester, ibuprofen is contraindicated as there is a risk of premature constriction/closure of the fetal ductus arteriosus with possible persistent pulmonary hypertension and renal dysfunction (see above). The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child (see section 4.3).

In limited studies, ibuprofen and its metabolites appear in the breast milk at very low concentrations and are unlikely to affect the breast-fed infant adversely.

See Section 4.4 regarding female fertility.

#### Phenylephrine

The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of fetal abnormalities with first trimester exposure to phenylephrine and due to the vasoconstrictive properties of phenylephrine the product should

be used with caution in patients with history of pre-eclampsia. Phenylephrine may reduce placental perfusion and until more information is available, use of phenylephrine should be avoided during pregnancy.

Animal data indicate that phenylephrine can decrease milk production, and therefore this medicine should not be used during breast feeding.

The effects of phenylephrine on male or female fertility have not been studied.

#### **4.7 Effects on ability to drive and use machines**

None expected at recommended doses and duration of therapy.

#### **4.8 Undesirable effects**

The incidences of undesirable effects are tabulated below. They are listed by system organ class and frequency defined as follows:

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  to  $< 1/10$ )

Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )

Rare ( $\geq 1/10,000$  to  $< 1/1,000$ )

Very rare ( $< 1/10,000$ )

Not known (cannot be estimated from the available data)

##### *Ibuprofen*

##### Blood and lymphatic system disorders

Very rare: Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

##### Immune system disorders

In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation, have been observed (see section 4.4).

Hypersensitivity reactions have been reported following treatment with buprofen and these may consist of:

- (a) Non-specific allergic reaction and anaphylaxis.
- (b) Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm or dyspnoea.
- (c) Various skin reactions, e.g. pruritis, urticaria, angioedema and, more rarely, exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The following list of adverse effects relates to those experienced with ibuprofen at OTC doses, for short-term use. In the treatment of chronic conditions, under long-term treatment, additional effects may occur.

#### Hypersensitivity reactions

Uncommon: Hypersensitivity reactions with urticaria and pruritus.

Very rare: Severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock).

Exacerbation of asthma and bronchospasm.

#### Nervous system disorders

Uncommon: Headache, dizziness and tinnitus.

Very rare: Aseptic meningitis - single cases have been reported very rarely.

#### Cardiac disorders

Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) 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).

Not known: Kounis syndrome.

#### Gastrointestinal disorders

The most commonly observed adverse events are gastrointestinal in nature.

Uncommon: Abdominal pain, nausea and dyspepsia.

Rare: Diarrhoea, flatulence, constipation and vomiting.

Very rare: Peptic ulcer, perforation and gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis and mouth ulceration.

Exacerbation of colitis and Crohn's disease (see Section 4.4).

#### Hepatobiliary disorders

Very rare: Liver disorders.

#### Skin and subcutaneous tissue disorders

Uncommon: Various skin rashes.

Very rare: Severe cutaneous adverse reactions (SCARs), including bullous reactions, Stevens-Johnson Syndrome, exfoliative dermatitis, erythema multiforme and toxic epidermal necrolysis, can occur.

Not known: 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, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.

Not Known: Ureteric colic, dysuria, renal tubular acidosis\*

#### Metabolism and Nutrition Disorders

Not Known: Decreased appetite, Hypokalaemia\*

\*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.

#### Phenylephrine

High blood pressure with headache and vomiting, probably only in overdose. Rarely, palpitations.

Also, rare reports of allergic reactions and occasionally urinary retention in males.

#### 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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

## **4.9 Overdose**

#### Ibuprofen

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

#### Symptoms

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 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).

Exacerbation of asthma is possible in asthmatics.

#### 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.

### Phenylephrine

Features of severe overdose of phenylephrine include haemodynamic changes and cardiovascular collapse with respiratory depression.

Treatment includes early gastric lavage and symptomatic and supportive measures. Hypertensive effects may be treated with an intravenous alpha-receptor blocking agent.

Phenylephrine overdose is likely to result in: nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), dysuria, urinary retention (most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy).

Additional symptoms may include hypertension, and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However, the amount required to produce serious phenylephrine toxicity would be greater than that required to cause paracetamol-related liver toxicity.

Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking medicinal products such as phentolamine.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Ibuprofen, combinations  
ATC-code: M01AE51

#### Ibuprofen

Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In humans ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

The therapeutic effect of ibuprofen in symptoms relating to the common cold and influenza has a duration of up to 8 hours.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400mg were taken within 8 hours before or within 30 minutes after immediate release acetylsalicylic acid (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these ex vivo 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).

### Phenylephrine

Phenylephrine is a post-synaptic alpha-receptor agonist with low cardioselective beta-receptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

## **5.2 Pharmacokinetic properties**

### Ibuprofen

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

Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1-2 hours. These times may vary with different dosage forms.

The half-life of ibuprofen is about 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations.

### Phenylephrine

Phenylephrine is absorbed from the gastrointestinal tract, but has reduced bioavailability by the oral route due to first-pass metabolism.

It retains activity as a nasal decongestant when given orally, the drug distributing through the systemic circulation to the vascular bed of the nasal mucosa.

When taken by mouth as a nasal decongestant, phenylephrine is usually given at intervals of 4-6 hours.

### Ibuprofen and phenylephrine combination

The ibuprofen component of this fixed combination (ibuprofen 200 mg plus phenylephrine hydrochloride 5 mg) is absorbed faster than standard ibuprofen 200 mg tablets, with therapeutic levels being reached in 26.4 minutes (from the fixed combination) as opposed to 55.2 minutes (for standard ibuprofen).

### **5.3 Preclinical safety data**

There are no findings of relevance to the prescriber other than those already mentioned elsewhere in the SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

- microcrystalline Cellulose
- Sodium starch glycolate
- Hypromellose
- Sodium stearyl fumarate
- Purified water

film: Opadry 200 white 200F280000 (consisting of polyvinyl alcohol, talc, macrogol, titanium dioxide, methacrylic acid copolymer, sodium bicarbonate,)

Purified water

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

24 months

### **6.4 Special precautions for storage**

Do not store above 30°C

### **6.5 Nature and contents of container**

PVC/PE/PVdC/AL blister

Blister: 12, 16 tablets

Not all pack sizes may be marketed

**6.6 Special precautions for disposal**

Not applicable.

**7 MARKETING AUTHORISATION HOLDER**

Thornton & Ross Ltd

Linthwaite  
Huddersfield  
HD7 5QH  
UK

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 00240/0382

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

31/07/2025

**10 DATE OF REVISION OF THE TEXT**

31/07/2025