Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vicks Action 200/30 mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	mg/tablet
Ibuprofen	200.0
Pseudoephedrine hydrochloride	30.0

Excipients: also includes Sunset yellow (E110).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet. (tablet).
Yellow film-coated tablet printed with a black triangle, for oral administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of head colds and influenza, including nasal congestion and to ease the pain of sore throats.

4.2 Posology and method of administration

Adults and children over 12 years:	Initial dose two tablets, then if necessary one or two tablets every four hours. Do not exceed six tablets in any 24 hour period.
	Not to be given to children under 12 years.
Elderly:	No special dosage modifications are required, unless renal or hepatic function is impaired in which case dosage should be assessed individually.

4.3 Contraindications

Patients with existing, or a history of, recurrent peptic ulceration/haemorrhage (two or more distinct episodes of proven ulceration or bleeding) or other gastrointestinal disorders.
Patients with history of bronchospasm, rhinitis, urticaria, particularly associated with therapy with aspirin or other non-steroidal anti-inflammatory drugs.
Patients with a history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
Hypersensitivity to any of the ingredients, aspirin or other NSAIDs.
Patients with severe heart failure or cardiovascular disease, hypertension, diabetes, hyperthyroidism, phaeochromocytoma, closed angle glaucoma, and prostatic enlargement.

This product should not be used by patients taking other sympathomimetic drugs, monoamine oxidase inhibitors or tricyclic antidepressants.

The product should not be used by children under the age of 12.

4.4 Special warnings and precautions for use

The labelling states:
"If symptoms persist for more than three days consult your doctor. As with all medicines containing pain relievers, if you are receiving regular treatment from your doctor consult him before taking this medicine. However, as with other pain relievers this medicine should not be taken if you have a stomach ulcer or other stomach disorder.

Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration"

The use of Vicks Action with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Patients with renal, cardiac or hepatic impairment - caution is required since the use of NSAIDs may result in deterioration of renal function.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal *(see section 4.2, Posology and method of administration).*

Gastrointestinal bleeding, ulceration and perforation: GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime 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, Contraindications),* and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk *(see below and 4.5, Interaction with other medicinal products and other forms of interaction)*

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, Interaction with other medicinal products and other forms of interaction).*

Caution (discussion with a 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.

Prolonged usage of NSAIDs in the elderly is not recommended. Where prolonged therapy is required patients should be reviewed regularly.

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

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as their condition may be exacerbated (See section 4.8 – undesirable effects).

NSAIDs can interfere with platelet function and should be used with caution in patients with intercranial haemorrhage and bleeding diathesis.

There is some 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.

Serious skin reaction, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs *(see section 4.8, Undesirable effects)*. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Vicks Action should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

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). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. 1200mg daily or less) is associated with an increased risk of myocardial infarction.

Do not exceed 6 tablets in any 24 hour period.
Not suitable for children under 12 years of age.
Asthma sufferers and anyone allergic to aspirin or who are pregnant should only take this medicine after consulting their doctor.
Warning: Do not exceed the stated dose.
Keep all medicines out of reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

Should not be given to patients receiving MAOI therapy or within 14 days of ceasing such treatment.

May potentiate the effects of other sympathomimetic agents, such as decongestants and appetite suppressants.

Care should be taken in patients treated with any of the following drugs as interactions have been reported:

Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin *(See section 4.4, Special warnings and precautions for use)*
Antihypertensives – reduced antihypertensive effect
Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs) – increased risk of gastrointestinal bleeding *(See section 4.4, Special warnings and precautions for use)*
Corticosteroids – increased risk of gastrointestinal ulceration or bleeding *(See section 4.4, Special warnings and precautions for use).*
Diuretics – reduced diuretic effect, diuretics can increase the nephrotoxicity of NSAIDs
Lithium - decreased elimination of lithium
Methotrexate – decreased elimination of methotrexate
Other NSAIDs – avoid concomitant use of two or more NSAIDs

4.6 Pregnancy and lactation

There is a possible association between the development of foetal abnormalities and first trimester exposure to pseudoephedrine and whilst no teratogenic effects have been demonstrated to ibuprofen in animal experiments, use during pregnancy should, if possible, be avoided.

Although ibuprofen appears in breast milk in very low concentrations, significant amounts of pseudoephedrine are secreted into breast milk and therefore use during lactation should be avoided.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur *(See section 4.4, Special warnings and precautions for use)*. Skin rashes, dyspepsia, gastrointestinal intolerance, nausea, vomiting, diarrhoea, flatulence, constipation, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease *(See section 4.4, Special warnings and precautions for use)* and sweating, giddiness, tachycardia, precordial pain, palpitations, restlessness, headache and insomnia have been reported following administration. Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Less frequently may cause difficulty in micturation, tremors, and thrombocytopenia, gastritis has been observed. Bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (very rare).

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, Special warnings and precautions for use)*.

4.9 Overdose

Symptoms of overdose include headache, nausea, vomiting, thirst, anxiety, restlessness, irritability, fever, sinus tachycardia, sweating, insomnia, dilated pupils, blurred vision, delusions and hallucinations, muscular weakness, difficulty in micturation, tremors, convulsions, coma, respiratory depression, hypertension, supraventricular and ventricular arrythmias.

Treatment consists of gastric lavage and if necessary correction of serum electrolytes. Symptomatic and supportive treatment should be undertaken, particularly with regard to the cardiovascular and respiratory systems. Convulsions should be controlled with intravenous diazepam. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension may be needed to be treated with an alpha-receptor blocking drug such as phentolamine. A beta-receptor blocking drug may be required to control cardiac arrythmias.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ibuprofen is a propionic acid derivative, having analgesic, antiinflammatory and antipyretic activity. The drugs therapeutic effects as a non-steriodal antiinflammatory are thought to result from inhibitory activity on prostaglandin synthesis.

Pseudoephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha and beta stimulant adrenergic activity and some stimulant effect on the central nervous system. The sympathomimetic effect of pseudoephedrine produces vasoconstriction which in turn relieves nasal congestion.

5.2 Pharmacokinetic properties

Ibuprofen is a proprionic acid derivative, having analgesic, antiinflammatory and antipyretic activity. The drugs therapeutic effects as a non-steriodal antiinflammatory are thought to result from inhibitory activity on prostaglandin synthesis.

Pseudoephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha and beta stimulant adrenergic activity and some stimulant effect on the central nervous system. The sympathomimetic effect of pseudoephedrine produces vasoconstriction which in turn relieves nasal congestion.

5.3 Preclinical safety data

Ibuprofen is rapidly absorbed from the gastro intestinal tract, peak serum concentration occurring 1-2 hours after administration. The elimination half life is approximately 2 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 protein.

Pseudoephedrine is absorbed from the gastro intestinal 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium phosphate
Microcrystalline cellulose
Povidone
Croscarmellose sodium
Magnesium stearate
Hypromellose
Talc
Opaspray yellow [contains colours quinoline yellow E104, sunset yellow E110 and titanium dioxide E171]
or Mastercote yellow [contains colours quinoline yellow E104, sunset yellow E110 and titanium dioxide E171]
Opacode black [contains black iron oxide E172, shellac, soya lecithin]

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25 °C.
Store in the original package.

6.5 Nature and contents of container

Blister trays of white pigmented 250m opaque PVC/40gsm PVDC laminate heat sealed to laquered 20m hard-temper aluminium foil, containing 12 tablets. One or two trays contained in a cardboard carton. Overall pack sizes are 12, 20 or 24 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Procter & Gamble
The Heights
Brooklands
Weybridge
Surrey
KT13 0XP
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0441/038/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisations: 24 January 1997

Date of last renewal: 24 January 2007

10 DATE OF REVISION OF THE TEXT

October 2008