SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

CONTAC Non Drowsy 12 Hour Relief

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Pseudoephedrine Hydrochloride 120 mg.

For excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Form: Prolonged-release capsule, hard

Description: Clear gelatin capsule, with CONTAC ND printed in black ink and containing pink prolonged-release granules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

CONTAC Non Drowsy 12 Hour Relief is a decongestant of the mucous membranes of the upper respiratory tract, especially the nasal mucosa and sinuses and is indicated for the symptomatic relief of conditions such as allergic rhinitis, the common cold and influenza.

4.2 Posology and method of administration

Adults:	One capsule to be taken in the morning and another at bedtime.
Children under 12 years:	Not recommended.
Elderly:	The healthy elderly may use an adult dose.
Route of administration:	Oral.

4.3 Contraindications

This product is contraindicated in patients with:

- Severe hypertension or uncontrolled hypertension
- Severe acute or chronic kidney disease/renal failure

Known hypersensitivity to pseudoephedrine hydrochloride or excipients. Individuals with severe hypertension or severe heart disease. Patients who are taking monoamine oxidase inhibitors (MAOI) or have taken them within the preceding two weeks. Patients receiving other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants).

4.4 Special warnings and precautions for use

CONTAC Non Drowsy 12 Hour Relief should be used with caution in patients suffering from mild to moderate hypertension, heart disease, arrhythmias, diabetes, hyperthyroidism, phaeochromocytoma, glaucoma and prostatic enlargement.

Caution should be exercised when using the product in the presence of moderate to severe renal impairment (particularly if accompanied by cardiovascular disease).

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3).
Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

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.

Risks of abuse
Pseudoephedrine carries the risk of abuse. Increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 4.2).

Patients with rare hereditary problems of fructose intolerance, glucose-

galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The following pack warnings and advice are recommended:

Do not chew or crush the capsule contents as this will interfere with the 12 hour action of the capsules.

If you are under the care of your doctor or receiving prescribed medicines or are pregnant or breast feeding, consult your doctor before taking this medicine.

Do not take with any other products for the relief of colds, congestion or hay fever.

If symptoms persist for more than 7 days consult your doctor.

Keep all medicines out of the reach and sight of children.

Warning. Do not exceed the stated dose.

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

4.5 Interaction with other medicinal products and other forms of interaction

Co-administration with MAOI (or within 2 weeks of stopping MAOI) may lead to hypertensive crisis.

Concomitant use of CONTAC Non Drowsy 12 Hour Relief with tricyclic antidepressants, sympathomimetic agents (such as decongestants, appetite suppressants and amfetamine-like psychostimulants) or with monoamine oxidase inhibitors and furazolidone, which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.

Because of their pseudoephedrine content, CONTAC Non Drowsy 12 Hour Relief may partially reverse the hypotensive action of drugs which interfere with sympathomimetic activity including bretylium, bethanidine, guanethidine, debrisoquine, methyldopa, alpha- and beta-adrenergic blocking agents.

4.6 Fertility, pregnancy and lactation

Do not use product if pregnant or breast feeding without medical advice.

4.7 Effects on ability to drive and use machines

Patients should be advised not to drive or operate machinery if affected by dizziness.

4.8 Undesirable effects

The following adverse reactions have been reported with pseudoephedrine:

Psychiatric disorders

Common (>1/100 to <1/10): nervousness, insomnia Uncommon (>1/1,000 to <1/100): agitation, restlessness

Rare (>1/10,000 to <1/1000): hallucinations (particularly in children)

Nervous System Disorders

Common (>1/100 to <1/10): dizziness

Not known: Posterior reversible encephalopathy syndrome (PRES) (see section 4.4), Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4)

Eye disorders

Frequency not known: Ischaemic optic neuropathy

Cardiac disorders

Rare (>1/10,000 to <1/1000): tachycardia, palpitations,

Vascular disorders

Rare (>1/10,000 to <1/1000): increased blood pressure*

*Increases in systolic blood pressure have been observed. At therapeutic doses, the effects of pseudoephedrine on blood pressure are not clinically significant.

Gastrointestinal disorders

Common (>1/100 to <1/10): dry mouth, nausea, vomiting

Skin and subcutaneous tissue disorders

Rare (>1/10,000 to <1/1000): rash, allergic dermatitis*

*A variety of allergic skin reactions, with or without systemic features such as bronchospasm, angioedema have been reported following use of pseudoephedrine

Renal and urinary disorders

Uncommon (>1/1,000 to <1/100): dysuria, urinary retention**

**Urinary retention is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy.

4.9 Overdose

Pseudoephedrine Hydrochloride

Symptoms
As with other sympathomimetics pseudoephedrine overdose will result in symptoms due to central nervous system and cardiovascular stimulation e.g. excitement, irritability, restlessness, tremor, hallucinations, hypertension, palpitations, arrhythmias and difficulty with micturition. In severe cases, psychosis, convulsions, coma and hypertensive crisis may occur. Serum potassium levels may be low due to extracellular to intracellular shifts in potassium.

Management
Treatment should consist of standard supportive measures. Beta-blockers should reverse the cardiovascular complications and the hypokalaemia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code R01B A02.

Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally-effective decongestant of the mucous membranes of the upper respiratory tract, especially the nasal mucosa and sinuses.

5.2 Pharmacokinetic properties

The product is a prolonged-release capsule presentation having a therapeutic action of up to 12 hours.

Pseudoephedrine is readily and completely absorbed from the gastrointestinal tract after oral administration, with no presystemic metabolism. Peak plasma levels are achieved after 1-2 hours. The plasma half–life varies from 4.3-7.0 hours in adults, but is shorter (3.1 hours) in children.

The volume of distribution ranges from 2.64 to 3.51 l/kg in both single and multiple dose studies.

There is little metabolism of pseudoephedrine in man with approximately 90% being excreted in the urine unchanged. Approximately 1% is eliminated by hepatic metabolism, by N-demethylation to norpseudoephedrine.

As a weak base, the extent of renal excretion is dependent on urinary pH. At low urinary pH, tubular resorption is minimal and urine flow rate will not influence clearance of the drug. At high pH (7.0), pseudoephedrine is extensively reabsorbed in the renal tubule and renal clearance will depend on urine flow rate.

Hepatic disease is unlikely to affect the pharmacokinetics of the drug. Renal impairment will result in increased plasma levels.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin, sucrose, starch, ethylcellulose, oleic acid, medium chain triglycerides, ammonium hydroxide (E527), hypromellose, titanium dioxide (E171), macrogol, carminic acid (E120), shellac (E904), black iron oxide (E172), simeticone, soya lecithin (E322).

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blisters of PVC 200 micron (polyvinylchloride)/PVDC 60 gsm (polyvinylidenechloride) backed with aluminium foil 20 micron, contained in a boxboard carton. Each pack contains 6 capsules.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Omega Pharma Ltd,
Wrafton, Braunton
Devon, EX33 2DL,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 02855/0084

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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