

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Vicks Cold & Flu Care Medinite Complete Syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS

	<u>Percentage w/v</u>	<u>Specification</u>
Dextromethorphan HBr	0.050	EP
Doxylamine succinate	0.025	USP
Paracetamol	2.000	EP
Pseudoephedrine HCl	0.200	BP

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the treatment of symptoms of the common cold, accompanied by runny nose, sneezing, headache, body ache, sore throat, cough and nasal congestion.

4.2 POSODOLOGY AND METHOD OF ADMINISTRATION

Oral administration.

Adults & Children over 12 years: 30ml in measuring cup at bedtime.

Elderly patients: Adult dose applies.

4.3 CONTRAINDICATIONS

Hypersensitivity to any of the ingredients

Cardiovascular disorders (hypertension, heart disease)

Hyperthyroidism

While currently taking MAOIs (monoamine oxidase inhibitors) or within 14 days of stopping taking MAOIs (see section 4.5)

Severe hepatic or renal insufficiency

Closed or narrow angle glaucoma

Phaeochromocytoma

Patients taking selective serotonin reuptake inhibitors (SSRIs, see section 4.5)

Concomitant use of other sympathomimetic decongestants

Patients taking beta blockers (see section 4.5)

Not to be used in Children under 12 years of age

4.4 SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

Do not exceed the recommended dose.

Do not take any other cough and cold medicine

Contains paracetamol. Patients should be advised not to take other paracetamol-containing products concurrently. Care is advised in the administration of paracetamol to patients with impaired hepatic function including those with non-cirrhotic alcoholic liver disease. The hazards of overdose are greater in those with alcoholic liver disease.

This product should be used with caution if the patient is suffering from the following conditions:

- Occlusive vascular disease
- Prostatic hypertrophy or urinary retention
- susceptibility to angle-closure associated with glaucoma
- diabetes mellitus

Ask a doctor before use if you have the following:

- a cough accompanied by excessive phlegm (mucus)
- a chronic or persistent cough such as occurs with smoking,
- emphysema
- asthma

If you are under the care of your doctor or are receiving prescribed medication or if you are pregnant, consult your doctor before using this product.

If any of the following occur, Vicks Cold & Flu Care Medinite Complete Syrup should be stopped:

- hallucinations
- restlessness
- sleep disturbances

If symptoms persist, consult your doctor.

Keep out of the reach and sight of children.

Contains alcohol. May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink and other CNS depressants.

Prolonged use without medical supervision is not advisable.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding.

Paracetamol may cause a marginal increase in blood levels of chloramphenicol, monoamine oxidase inhibitors, antihypertensives, beta-blockers.

Not recommended for patients currently receiving or within 14 days of stopping therapy with monoamine oxidase inhibitors (MAOI) and/ or reversible inhibitors of monoamine oxidase (RIMA) and moclobemide due to the risk of serotonin syndrome

Drugs which induce liver enzymes (e.g. alcohol, anticonvulsants etc) may increase the hepatotoxicity of paracetamol, particularly after overdose.

Pseudoephedrine may reduce the efficacy of beta-blocking drugs, methyl dopa or other anti-hypertensive drugs including adrenergic neurone blockers.

There is a possible increased risk of hypertension and arrhythmias when tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants are given with sympathomimetics such as pseudoephedrine.

Possible additive cardiovascular toxicity may occur when sympathomimetics are given with antiparkinsonian drugs such as bromocriptine

There is an increased risk of dysrhythmias when cardiac glycosides are given with sympathomimetics such as pseudoephedrine.

There is an increased risk of ergotism when ergot alkaloids (ergotamine & methysergide) are given with sympathomimetics such as pseudoephedrine.

Dextromethorphan is primarily metabolised by the cytochrome P450 isoenzyme CYP2D6; there is a possibility of interactions with inhibitors of this enzyme, including amiodarone, haloperidol, propafenone, quinidine, SSRIs, and thioridazine.

Dextromethorphan and doxylamine might exhibit additive CNS depressant effects with alcohol, antihistamines, psychotropics, and other CNS depressant drugs e.g., barbiturates, hypnotics, opioid analgesics and anxiolytic sedatives.

4.6 PREGNANCY AND LACTATION

Epidemiological studies in human pregnancy have shown no effects due to paracetamol used in the recommended dosage. However, paracetamol should be avoided in pregnancy unless considered essential by the physician.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Due to insufficient evidence on the use of the product in pregnancy and lactation, use of the product should be avoided unless on the advice of a physician.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

May cause drowsiness. Those affected should not drive or operate machinery.

4.8 UNDESIRABLE EFFECTS

In general no severe undesirable effects are expected.

Cardiac disorders:

Pseudoephedrine may rarely be associated with palpitations, tachycardia and other cardiac dysrhythmias and hypertension.

Doxylamine may rarely cause hypotension.

Blood and lymphatic system disorders:

Very rarely blood dyscrasias e.g. thrombocytopenia, agranulocytosis, haemolytic anaemia, neutropenia, leucopenia, pancytopenia have been reported with paracetamol or doxylamine, but these were not necessarily causally related.

Nervous system disorders:

Drowsiness is common with doxylamine and may occur rarely with dextromethorphan.

Other side effects that are more common with antihistamines such as doxylamine are headache, blurred vision and psychomotor impairment. It rarely causes depression.

Dextromethorphan is also rarely associated with dizziness.

Symptoms of central nervous system excitability and excitation may occur with pseudoephedrine as with other sympathomimetic amines, including sleep disturbance (insomnia), anxiety and restlessness. Hallucinations have been reported rarely.

Gastrointestinal disorders:

Anorexia, nausea and vomiting are common with sympathomimetics and may occur with pseudoephedrine. Dry mouth, constipation and increased gastric reflux may occur with antihistamines such as doxylamine.

Gastrointestinal disturbances that may rarely occur with doxylamine or with dextromethorphan include nausea, vomiting, abdominal pain and diarrhoea.

Renal and urinary disorders:

Urinary retention has been reported occasionally in men receiving pseudoephedrine: prostatic enlargement could have been an important predisposing factor. Antihistamines such as doxylamine may cause urinary retention or difficulty passing urine.

Skin and subcutaneous disorders:

Hypersensitivity including skin rash and urticaria may occur rarely with paracetamol. Skin rashes, with or without irritation; have rarely been reported with pseudoephedrine and also with dextromethorphan.

Immune system disorders:

There are rare reports of allergic or hypersensitivity reactions with paracetamol and with doxylamine, including skin rashes, urticaria, anaphylaxis and bronchospasm.

4.9 **OVERDOSE**

4.9.1 **Symptoms**

Paracetamol:

Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported.

Other symptoms may include CNS depression, cardiovascular effects and renal damage.

Dextromethorphan or Doxylamine:

Symptoms such as excitation, mental confusion, convulsions and respiratory depression may occur after overdose with dextromethorphan or doxylamine. It is thought to be of low toxicity, but the effects in dextromethorphan overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Pseudoephedrine:

Central nervous and cardiovascular symptoms may occur with overdose. These may include agitation, insomnia, tremors or convulsions, hypertension and cardiac arrhythmias

4.9.2 **Treatment of overdose**

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who has ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose may be required. General supportive measures must be available.

Treatment of other symptoms is by symptomatic management.

Treatment of dextromethorphan overdose should be symptomatic and supportive. Naloxone has been used successfully to reverse central or peripheral opioid effects of dextromethorphan in children (0.01mg/kg body weight).

5. **PHARMACOLOGICAL PROPERTIES**

5.1 **PHARMACODYNAMIC PROPERTIES**

Paracetamol:	Analgesic/antipyretic.
Dextromethorphan HBr:	Anti-tussive.
Doxylamine succinate:	Antihistamine, anticholinergic.

Pseudoephedrine hydrochloride: Sympathomimetic agent - nasal decongestant.

5.2 **PHARMACOKINETIC PROPERTIES**

Paracetamol:	Metabolised in the liver and excreted in the urine as glucuronide and sulphate conjugates.
Dextromethorphan HBr:	Metabolised in the liver and excreted as unchanged dextromethorphan and demethylated morphinian compounds.
Doxylamine succinate:	Is believed to be metabolised in the liver and excreted mainly as metabolites in the urine.
Pseudoephedrine hydrochloride:	Is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine.

5.3 **PRE-CLINICAL 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**

Ethanol 96%
Sodium citrate
Citric acid monohydrate
Sodium benzoate
Polyethylene glycol 6000
Sucrose
Glycerol
Anethole
Quinoline yellow (E104)
Indigotin blue (E132)
Water, purified

6.2 **INCOMPATIBILITIES**

None known.

6.3 **SHELF-LIFE**

36 months.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

6.5 NATURE AND CONTENT OF CONTAINER

180 ml clear flint glass bottle with wadless polypropylene screw cap or white polypropylene child resistant closure.

6.6 INSTRUCTIONS FOR USE/HANDLING

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Procter & Gamble (Health & Beauty Care) Limited
The Heights
Brooklands
Weybridge
Surrey
KT13 0XP

8. MARKETING AUTHORISATION NUMBER

MA 028/00102

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th April 2007

10. DATE OF (PARTIAL) REVISION OF TEXT

22nd August 2012