Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
PHILCOLIN DM

2. Qualitative and quantitative composition

Each 5 ml spoonful contains:
Dextromethorphan Hydrobromide BP 10mg,
Phenylephrine Hcl BP 5mg,
Cetirizine Hcl BP 5mg
Racementhol BP 1.5mg

This product contains ethanol.

For a full list of excipients, see section 6.1

3. Pharmaceutical form
Oral suspension

4. Clinical particulars

4.1 Therapeutic indications

PHILCOLIN DM is a cough suppressant used in the symptomatic relief of unproductive cough associated with colds. The combined effect of Cetirizine and decongestant or Phenylephrine Hydrochloride relieve irritation and congestion. The antitussive effect of Dextromethorphan Hydrobromide helps relieve the discomfort or nuisance of frequent unproductive cough. philcolin DM is useful in both children and adults as a cough suppressant.

4.2 Posology and method of administration

Adult:
Take 10 mL 2-3 times daily or as directed by the physician.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
The drug should be avoided in patients who are known to be allergic to any one of the components of the mixture. The preparation may cause drowsiness or in some cases excitability.
It should not be given to patients who have high blood pressure, organic heart disease, thyroid disease, diabetes mellitus, glaucoma and those who are on prescription drugs for depression. Dextromethorphan should not be used in patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of

stopping MAOI treatment (see section 4.5). There is a risk of serotonin syndrome with the concomitant use of dextromethorphan and MAOIs and the concomitant use of these medications may cause a rise in blood pressure and/or hypertensive crisis (see section 4.5).

This product is contraindicated in patients taking serotonin reuptake inhibitors (SSRIs, see section 4.5).

Dextromethorphan, should not be given to patients in, or at risk of developing respiratory failure.

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

4.4 Special warnings and precautions for use

The drug should be avoided in patients who are known to be allergic to any one of the components of the mixture. The preparation may cause drowsiness or in some cases excitability.
It should not be given to patients who have high blood pressure, organic heart disease, thyroid disease, diabetes mellitus, glaucoma and those who are on prescription drugs for depression.

4.5 Interaction with other medicinal products and other forms of interaction

The drug should be avoided in patients who are known to be allergic to any one of the components of the mixture. The preparation may cause drowsiness or in some cases excitability.
It should not be given to patients who have high blood pressure, organic heart disease, thyroid disease, diabetes mellitus, glaucoma and those who are on prescription drugs for depression.

4.6 Pregnancy and Lactation

Although dextromethorphan has been in widespread use for many years without apparent ill consequence, there are no specific data on its use during pregnancy. Caution should therefore be exercised by balancing the potential benefit of treatment against any possible hazards. It is not known whether dextromethorphan or its metabolites are excreted in human milk.

Phenylephrine is excreted in breast milk but not in a clinically significant amount.

For cetirizine prospectively collected data on pregnancy outcomes do not suggest potential for maternal or foetal/embryonic toxicity above background rates. Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Cetirizine is excreted in human milk at concentrations representing 25% to 90% those measured in plasma, depending on sampling time after administration. Therefore, caution should be exercised when prescribing cetirizine to lactating women.
Menthol is chiefly used to relieve symptoms of bronchitis, sinusitis, and is especially useful when it is desired to liquefy thick, tenacious sputum.

4.7 Effects on ability to drive and use machines

The preparation may cause drowsiness. Do not drive until you know how the medicine affects you.

4.8 Undesirable effects

Dextromethorphan

Adverse drug reactions (ADRs) identified during clinical trials and post-marketing experience with dextromethorphan are included in the table below by System Organ Class (SOC).
The frequencies are provided according to the following convention:
Very common ≥ 1/10
Common ≥ 1/100 and < 1/10
Uncommon ≥ 1/1,000 and <1/100
Rare ≥ 1/10,000 and <1/1,000
Very rare <1/10,000, including isolated reports
Not known (cannot be estimated from the available data)
ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available, or 2) when incidence cannot be estimated, frequency category is listed as 'Not known'.

System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Psychiatric Disorders	Not known Not known Not known Not known	Agitation Confusional state Drug dependence Insomnia
Nervous System Disorders	Not known Not known Not known Not known	Dizziness Psychomotor hyperactivity Seizure Somnolence
Respiratory, thoracic and	Not known	Respiratory depression

mediastinal Disorders		
Gastrointestinal Disorders	Not known Not known Not known Not known Not known	Abdominal pain Diarrhoea Gastrointestinal disorder Nausea Vomiting
Skin and Subcutaneous Tissue Disorders	Not known Not known Not known Not known	Angioedema Pruritus Rash Urticaria
General disorders and administration site conditions	Unknown	Drug withdrawal syndrome

Clinical studies have shown that cetirizine at the recommended dosage has minor undesirable effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.

Although cetirizine is a selective antagonist of peripheral H_1-receptors and is relatively free of anticholinergic activity, isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported. Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with cetirizine hydrochloride.

The following adverse events have been observed in clinical trials with phenylephrine and may therefore represent the most commonly occurring adverse events.

Body System	**Undesirable effect**
Psychiatric disorders	Nervousness, irritability, restlessness, and excitability
Nervous system disorders	Headache, dizziness, insomnia
Cardiac disorders	Increased blood pressure
Gastrointestinal disorders	Nausea, Vomiting, diarrhoea

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 pharmacy and poison board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

Should overdose occur symptomatic or supportive treatment is recommended

5. Pharmacological properties

5.1 Pharmacodynamic properties

Phenylephrine Hydrochloride is a sympathomimetic decongestant.
Dextromethorphan is the dextrorotatory isomer of 3-methoxy-N-methyl-morphinan. It is a synthetic morphine derivative that, in contrast to its levorotatory isomer, has no significant analgesic, respiratory depressant or physical dependency properties at recommended doses.

Dextromethorphan is a non-opioid antitussive drug. It exerts its antitussive activity by acting on the cough centre in the medulla oblongata, raising the threshold for the cough reflex. The onset of antitussive effects are realised within 15 to 30 minutes of oral administration, lasting for approximately 3 to 6 hours.

The major metabolite of dextromethorphan, dextrorphan, binds with high affinity to σ -receptors to produce its antitussive activity without exhibiting the classic opiate effects that occur from binding into μ - and δ -receptors. Dextrorphan also exhibits binding activity at serotonergic receptors and was shown to enhance serotonin activity by inhibiting the reuptake of serotonin. In larger than therapeutic doses, dextrorphan is also an antagonist of N-methyl-D-aspartate (NMDA) receptors.

Cetirizine, a human metabolite of hydroxyzine, is a potent and selective antagonist of peripheral H_1-receptors. *In vitro* receptor binding studies have shown no measurable affinity for other than H_1-receptors. In addition to its anti-H_1 effect, cetirizine was shown to display anti-allergic activities: at a dose of 10 mg once or twice daily, it inhibits the late phase recruitment of eosinophils, in the skin and conjunctiva of atopic subjects submitted to allergen challenge.

5.2 Pharmacokinetic properties

Dextromethorphan is rapidly absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine as unchanged dextromethorphan and demethylated metabolites including dextrorphan, which has some cough suppressant activity.

Phenylephrine has low oral bioavailability owing to irregular absorption and first-pass metabolism by monoamine oxidase in the gut and liver. When injected subcutaneously or intramuscularly it takes 10 to 15 minutes to act; subcutaneous and intramuscular injections are effective for up to about 1 hour and up to about 2 hours, respectively. Intravenous injections are effective for about 20 minutes.
Cetirizine is rapidly absorbed from the gastrointestinal tract after oral administration, peak plasma concentrations being attained within about one hour. Food delays the time to peak plasma concentrations but does not decrease the amount of drug absorbed. It is highly bound to plasma proteins and has an elimination half-life of about 10 hours. Cetirizine has been detected in breast milk. Cetirizine is excreted primarily in the urine mainly as unchanged drug. Cetirizine does not appear to cross the blood-brain barrier to a significant extent.
After absorption, menthol is excreted in the urine and bile as a glucuronide.

5.3 Preclinical safety data

Dextromethorphan
General toxicology
Acute oral toxicity studies conducted with Dextromethorphan report the following LD50 values (mg/kg): mouse, 210 and rat, 116. Acute subcutaneous toxicity with Dextromethorphan reports the LD50 value (mg/kg): mouse, 112. Acute intravenous toxicity with Dextromethorphan reports the LD50 value (mg/kg): rat, 16.3.

Repeat dose toxicity studies conducted in rats for 13 weeks duration at doses up to 100 mg/kg and 27 weeks at 10 mg/kg, and of 14 weeks in dogs by oral gavage at doses up to 4 mg/kg on five days per week. The only effect recorded was of reduced body weight gain in the rat 13-week study at the highest dose.

Genetic Toxicology
Dextromethorphan hydrobromide was negative in the bacterial reverse mutation assay (Ames test). Dextromethorphan 39 mg/kg is reported to be negative in in-vivo mouse micronucleus test and comet assay. Dextromethorphan was reported to be negative in in vitro chromosome aberration assay tested up to 200 µ g/ml.

Carcinogenicity
There are no known reports of animal carcinogenicity studies for Dextromethorphan. The overall weight of evidence for Dextromethorphan and its structural analogues, support the conclusion that this class of phenanthrene-based chemicals, and Dextromethorphan, in particular, are not genotoxic in vitro or in vivo

Teratogenicity

There was no association between dextromethorphan and malformations.

Fertility
Mating, gestation, fertility, littering and lactation were studied in rats at doses up to 50 mg/kg and no adverse effects were found.

Preclinical safety data on these active ingredients in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product and which have not already been mentioned elsewhere in this SmPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sodium Citrate
Citric Acid
Sodium Benzoate
Sodium Saccharin
Natrosol Gum
Ethanol 96%
Tartrazine Yellow colour
Raspberry Liquid flavour
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf-Life

3 years

6.4 Special Precautions for storage

Store in a dry place below 30°C. Protect from light

6.5 Nature and Content of container

Amber glass bottle containing 100ml and 60ml Philcolin DM. Supplied with a measuring spoon.

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing Authorization Holder

COMET HEALTHCARE LIMITED

8. Marketing Authorization Number
CTD6746

9. Date of first authorization/renewal of the authorization
28/03/2023

10. Date of revision of the text
06/05/2025