1 PRODUCT NAME

Duro-Tuss Dry Cough Lozenge (Lemon and Orange).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains pholcodine 5.5 mg and cetylpyridinium chloride 1.33 mg.

Excipients with known effects: Sucralose and isomalt.

For the full list of excipients (see section 6.1).

3 PHARMACEUTICAL FORM

Lemon flavour: Round, flat bevelled lozenges, 19mm diameter. Firm, smooth surfaces. Lozenges not adhering to each other. Colour: yellow.

Orange flavour: Round, flat bevelled lozenges, 19mm diameter. Firm, smooth surfaces. Lozenges not adhering to each other. Colour: orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Relives dry cough and associated sore throats.

4.2 Dose and method of administration

Dosage

Adults and children aged 12 years & over: Two lozenges. Every 3 hours as required (maximum of 12 lozenges per day).
Children aged 6-11 years: One lozenge. Every 3 hours as required (maximum of 6 lozenges per day).
Children under 6 years: Do not use.

Method of administration

For oropharyngeal use. Slowly dissolve lozenge in mouth, one at a time. Do not swallow.

4.3 Contraindications

- Children under 6 years of age
- Hypersensitivity to the pholcodine, cetylpyridinium chloride, or to any of the excipients listed in section 6.1
- Patients in, or at risk of developing respiratory failure or during acute asthma attacks, as it may depress respiration
- Patients with chronic bronchitis, COPD, bronchiolitis or bronchiectasis due to sputum retention
- Patients with renal or hepatic failure
- Patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment (see also section 4.5).

4.4 Special warnings and precautions for use

Use with caution in patients with:

- Liver or renal disease
- Chronic or persistent cough, or where cough is accompanied by excessive secretions
- Asthma, including an acute asthma attack or where cough is accompanied by excessive secretions.

Severe cutaneous adverse reactions (SCARs) including acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in patients treated with pholcodine-containing products, most likely in the first week. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, stop taking immediately.

Concomitant use with any other cough and cold medicines medicines intended to treat the symptoms of the common cold is not recommended.

Cross-reactivity leading to serious allergic reactions (anaphylaxis) have been reported between pholcodine and Neuromuscular Blocking Agents (NMBAs). A precise at-risk period of time between the exposures of pholcodine and NMBAs has not been determined. Clinicians should be aware of this potential in case of future anaesthetic procedures involving NMBAs.

Use of pholcodine with alcohol or other central nervous system (CNS) depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.

Duro-Tuss lozenges contains isomalt, which may have a laxative effect or cause diarrhoea and patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

Do not use in patients taking MAOIs or within 14 days of stopping treatment.

Interaction with neuromuscular blocking agents (anaphylaxis) has been reported (see Section 4.4).

The reduction in blood pressure caused by antihypertensives may accentuate the hypotensive effects of pholcodine. Diuretics may have the same effect.

Pholcodine may enhance the sedative effect of CNS depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers (phenothiazines and tricyclic antidepressants).

4.6 Fertility, pregnancy and lactation

Category A

The safety of pholcodine during pregnancy and lactation has not been established. Risk vs benefit must be considered before using pholcodine during pregnancy or lactation. There is a risk of gastric stasis in the mother during labour which may lead to inhalation pneumonia. Teratogenic effects in humans have not been documented but controlled studies have not been done, nor have studies in animals been documented for pholcodine.

Use in lactation: It is not known whether pholcodine is excreted in breast milk or whether it has a harmful effect on the breastfeeding infant.

Therefore, Duro-Tuss Dry Cough Lozenge is not recommended during pregnancy unless it is considered essential by the physician.

4.7 Effects on ability to drive and use machines

This medicine may cause drowsiness and therefore may impair the ability to perform activities requiring mental alertness, such as driving and operating machinery. Patients may be at risk whilst driving or operating machinery. If affected patients should not drive a vehicle or operate machinery.

4.8 Undesirable effects

Pholcodine

The following side effects may be associated with the use of pholcodine:

Nervous system disorders: Occasional drowsiness, dizziness, excitation, confusion

Respiratory, thoracic and mediastinal disorders: Sputum retention

Gastrointestinal disorders: Vomiting, gastrointestinal disturbances (nausea and constipation)

Skin and subcutaneous tissue disorders: Skin reactions including rash.
Acute generalized exanthematous pustulosis (see section 4.4).

Immune system disorders: Hypersensitivity reactions and anaphylaxis.

Cetylpyridinium chloride
Occasional irritant or hypersensitivity reactions.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose
For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

Pholcodine is thought to be of low toxicity, but the effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs. A toxic dose in children is reported to be about 200 mg. Symptoms of pholcodine overdose include nausea, drowsiness, restlessness, excitement, ataxia and respiratory depression.

Cetylpyridinium chloride may cause corrosive damage to the gastrointestinal tract, leading to pain, nausea, vomiting and diarrhoea. Signs of toxicity may also include euphoria, slurred speech, muscular incoordination, impairment of consciousness and coma.

Management: Treatment of overdose should be symptomatic and supportive. In cases of severe poisoning the specific narcotic antagonist nalaxone may be used.

Information for children:
Nalaxone has been used successfully to reverse central or peripheral opioid effects in children (0.01mg/kg body weight). Another treatment option is activated charcoal (1g/kg body weight) if more than 4mg/kg has been ingested within 1 hour, provided the airway can be protected

In children especially, overdosage could lead to hypoglycaemia, which should be treated with either oral or intravenous glucose.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pholcodine is a cough suppressant with mild sedative but little analgesic or euphorigenic activity. It suppresses the cough reflex by a direct central action, probably in the medulla or pons.

Cetylpyridinium chloride: Cationic antiseptic with activity against both gram positive and gram-negative organisms.

5.2 Pharmacokinetic properties
Pholcodine: Maximum plasma concentrations are attained at 4 to 8 hours after an oral dose. The elimination half-life ranges from 32 to 43 hours and volume of distribution is 30-49 L/kg. Pholcodine is protein bound to the extent of 23.5%. Pholcodine is metabolised in the liver but undergoes little conjugation. There is little or no metabolism of pholcodine to morphine.

Cetylpyridinium chloride: Oral doses are generally poorly absorbed and therefore relatively large amounts of the compound are eliminated in faeces. No readily available data regarding its metabolism is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lemon flavour:
Isomalt
Sucralose
Menthol
Citric acid
Quinoline yellow
Lemon flavour 987317

Orange flavour:
Isomalt
Sucralose
Menthol
Citric acid
Sunset yellow FCF
Orange flavour 051239A

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from date of manufacture.

6.4 Special precautions for storage

Store at or below 30^0C.

6.5 Nature and contents of container

Blister pack, PVC/PVDC/Aluminium foil: 24 lozenges.

6.6 Special precautions for disposal

No special requirements.

7 MEDICINE SCHEDULE

Pharmacist Only Medicine

8 SPONSOR

iNova Pharmaceuticals (New Zealand) Limited
c/- Simpson Grierson
88 Shortland Street,
Auckland 1141
Toll-free number: 0508 375 394

9 DATE OF FIRST APPROVAL

16 March 2023

10 DATE OF REVISION OF THE TEXT

16 March 2023

SUMMARY TABLE OF CHANGES

Date	Changes
All	New data sheet