NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Duro-Tuss Dry Cough Liquid Forte

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL of the medicine contains 15 mg pholcodine.

Excipients with known effect:
Sodium benzoate, saccharin sodium and sorbitol.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

A clear yellow-orange, slightly viscous solution with an odour of apricot.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Temporary relief of stubborn dry coughs.

4.2 Dose and method of administration

For oral administration.

Age	Dosage	How often
Adults & children 12 years & over	5 mL	Every 6 hours as required (Maximum 4 times a day)
Children under 12 years	Do not use	

4.3 Contraindications

- Children under the age of 12 years.
- Hypersensitivity to pholcodine or any of the excipients listed in section 6.1.
- Patients in, or at risk of, developing respiratory failure or during acute asthma attacks (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.

Pholcodine should be used with caution in patients with chronic or persistent cough, 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 If signs and symptoms suggestive of these reactions appear, Duro-Tuss Dry Cough Liquid Forte should be withdrawn immediately.

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.

Concomitant use of Duro-Tuss Dry Cough Liquid Forte with other medicines intended to treat the symptoms of the common cold is not recommended.

This product contains sorbitol which may have a laxative effect or cause diarrhoea in some people.

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 Liquid Forte 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 can impair cognitive function and can affect a patient's ability to drive safely or operate machinery.

Patients should therefore exercise caution before driving or use of machinery until they know Duro-Tuss Dry Cough Liquid Forte does not adversely affect their performance.

4.8 Undesirable effects

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.

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

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: These include nausea, drowsiness, restlessness, excitement, ataxia and respiratory depression.

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.

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

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.

Pharmacotherapeutic group: R05DA Opium alkaloids and derivatives

ATC code: R05DA08 pholcodine

5.2 Pharmacokinetic properties

Maximum plasma concentrations are attained at 4 to 8 hours after an oral dose. The elimination half-life ranges from 32–43 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.

5.3 Preclinical safety data

There are no preclinical data of relevance which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid
Disodium edetate
Hyetellose
Purified water
Saccharin sodium
Sodium benzoate
Sodium citrate
Sorbitol
Sunset yellow FCF colourant
Apricot flavour 012500

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 30°C.

6.5 Nature and contents of container

Amber PET bottle with polypropylene CRC tamper evident wadded cap.
Pack size: 100 and 200 mL

6.6 Special precautions for disposal

No special requirements

7 MEDICINE SCHEDULE

S3 – Pharmacist Only medicine

8 SPONSOR

iNova Pharmaceuticals (New Zealand) Limited
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9 DATE OF FIRST APPROVAL

16 March 2023

10 DATE OF REVISION OF THE TEXT

16 March 2023

SUMMARY TABLE OF CHANGES

Section changed:	**Summary of new information:**
All	New data sheet