NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Gees Linctus

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Anhydrous Morphine 0.0165% w/v

Squill 1.67% w/v

Excipient(s) with known effect

For the full list of excipients, see section 6.1.

Contains 20% v/v alcohol. Contains honey.

3. PHARMACEUTICAL FORM

Linctus

Presentation

A straw coloured to light brown opalescent liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief from a wet, productive and irritating cough.

4.2 Dose and method of administration

Adults and children over 12 years: Take 5 mL sipped slowly or added to 10 mL of warm water and sipped slowly.
To be taken up to 3 to 4 times daily as required.

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

Children under 12 years: Not recommended.

The elderly: Use with care, not exceeding the recommended adult dose.

4.3 Contraindications

Contraindicated in patients with known hypersensitivity to any of the ingredients. Also contraindicated in patients with cardiac disorders and in impaired hepatic or renal function.
Contraindicated in cases of moderate to severe respiratory depression, alcoholism, head injuries and conditions in which intracranial pressure is raised, also in acute asthma, and heart failure secondary to chronic lung disease.

Contraindicated in patients receiving treatment with monoamine oxidase inhibitors or within 14 days of stopping such treatment.

4.4 Special warnings and precautions for use

The linctus should be given with caution to patients with: hypothyroidism, adrenocortical insufficiency, inflammatory or obstructive bowel disorders, prostatic hypertrophy, shock, myasthenia gravis, hypotension, the elderly and patients with general debilitation. Reduced doses may be required in these conditions.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This product is not recommended for children under 12 years of age.

Consult a Doctor /Pharmacist before using with other medicines intended to treat the symptoms of the common cold.

This medication may cause drowsiness. If affected, do not drive a vehicle or operate heavy machinery within 8 hours of taking this medicine. Avoid alcohol.

If coughing persists for more than 7 days consult your doctor. Do not use for prolonged periods.

Keep out of reach of children.

Do not take if allergic to any of the ingredients, have heart, liver or kidney disease, or breathing difficulty or suffer from alcoholism or raised pressure in the head.

4.5 Interaction with other medicines and other forms of interaction

The linctus should not be taken by patients receiving monoamine-oxidase inhibitors or within 14 days of stopping such treatment.

Narcotic analgesics cause delayed absorption of mexiletine, they also cause potentiation of the effects of hypnotics and anxiolytics and other CNS depressants. They have opposing effects on gastro-intestinal activity to domperidone and metoclopramide. Toxicity of squill glycosides may be increased when given in combination with thiazides

or loop diuretics, as these cause hypokalaemia and hypomagnesaemia which may lead to cardiac arrhythmias.

Hypokalaemia may result from simultaneous treatment with corticosteroids, amphotericin, sodium polystyrene sulphonate and carbenoxolone.

Absorption may be affected by intestinal absorptive agents and antacids including metoclopramide and propantheline. Simultaneous administration of spironolactone, phenobarbital or rifampicin may reduce renal excretion.

4.6 Fertility, pregnancy and lactation

As the product contains anhydrous morphine 0.0165% w/v and 20.0% v/v ethanol it is not recommended if a patient is pregnant, trying to become pregnant or breastfeeding.

4.7 Effects on ability to drive and use machines

At the recommended dose this product is unlikely to cause drowsiness, however this medicine can impair cognitive function and can affect a patient's ability to drive safely.

4.8 Undesirable effects

Narcotic analgesics may cause nausea, vomiting, constipation, drowsiness, confusion. Larger doses may cause respiratory depression, difficulty with micturition, urticaria, pruritis, flushing and hypotension. Tolerance gradually develops with long term use although not constipation, and dependence is liable to be caused. Squill contains cardiac glycosides and may cause nausea, vomiting and anorexia, diarrhoea and abdominal pain may also occur.

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

Signs of morphine overdosage include pin-point pupils, depressed respiration, circulatory failure, pulmonary oedema, convulsions, renal failure and coma.
Gastric lavage should be performed as soon as possible after ingestion, and intensive supportive therapy carried out.
Naloxone may be given as an antidote (initially 0.8 - 2.0 mg, to a maximum of 10mg, by intravenous injection).

Common symptoms of digoxin overdosage are headache, facial pain, fatigue, weakness, dizziness, drowsiness, disorientation, mental confusion, bad dreams and more rarely

delirium, acute psychoses, and hallucinations. Visual disturbances including blurred and misted vision may occur. Colour vision may be affected with objects appearing yellow or occasionally green, red, brown, blue or white. Convulsions have been reported.

Large doses of squill produce nausea, vomiting and diarrhoea, it has a digitalis-like effect on the heart. Supraventricular or ventricular arrhythmias and defects of conduction may be an early indication of excessive dosage.

Treatment of acute digoxin poisoning consists of emptying the stomach by emesis or aspiration and lavage. Activated charcoal may be given. Cardiac toxicity should be treated under ECG control and serum electrolytes should be monitored. Anti-arrhythmic treatment may be necessary and should be determined by the specific arrhythmia present. Atropine may be given intravenously to control bradycardia, and in patients with heart block; cardiac pacing may be necessary if atropine is not effective. Colestyramine or colestipol may be of use in increasing the elimination of cardiac glycosides.

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

R05F A02 - Cough suppressants and expectorants, combinations – opium derivatives and expectorants.

Morphine and other related opioids are effective for the suppression of cough. They depress the cough reflex, at least in part by a direct effect on a cough centre in the medulla.

Squill has an irritant effect on the gastric mucosa, it has a reflex expectorant action.

5.2 Pharmacokinetic properties

Opioids are readily absorbed from the gastrointestinal tract. The major pathway for detoxification of morphine is conjugation with glucuronic acid.
Small amounts of free morphine and larger amounts of conjugated morphine are excreted in the urine, accounting for most of the administered drug. 90% of total excretion occurs during the first day, however, traces may be detectable in the urine for over 48 hours. The major route of elimination of the metabolites is by glomenilar filtration. 7-10% of administered morphine eventually appears in the faeces, this comes mostly from the bile as conjugated morphine. Enterohepatic circulation of morphine and morphine glucuronide occurs, this accounts for the presence of morphine in the urine several days after the last dose.

Squill glycosides are poorly absorbed from the gastrointestinal tract, they are of short acting duration and are not cumulative. The drug promotes mild gastric irritation, causing a reflex secretion from the bronchioles.

5.3 Preclinical safety data

No data of relevance to the prescriber, which is additional to that included in other sections of the datasheet.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 20% v/v
Anise oil
Camphor
Honey
Purified water
Sugar premium liquid and granules
Tolu balsalm
Benzoic acid
Methyl hydroxybenzoate

Free from gluten, artificial colours and artificial sweeteners.

6.2 Incompatibilities

No major incompatibilities known.

6.3 Shelf life

24 months from date of manufacture.

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Gees Linctus
200 mL Bottle, glass
2 Litre Bottle, plastic

Note: Not all pack sizes are marketed.

6.6 Special precautions for disposal

None.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

PSM Healthcare Ltd trading as API Consumer Brands
14-16 Norman Spencer Drive
Manukau City
AUCKLAND 2241
Freephone: 0508 776 746

9. DATE OF FIRST APPROVAL

14 June 2001

10. DATE OF REVISION OF THE TEXT

14th April 2020

SUMMARY TABLE OF CHANGES

Section changes	Summary of new information
All sections	New datasheet for Gees Linctus.