Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Coldenza 6C Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Gelsemium sempervirens 6C

Excipient(s) with known effect:

Lactose 79.21% w/w

Sucrose 19.27% w/w

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Biconvex circular white to off-white tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A Homeopathic Medicinal product used within the homeopathic tradition for the symptomatic relief of colds and related flu-like symptoms.

4.2 Posology and method of administration

For oral use

Adults, the elderly and children over 12 years: Take 2 tablets every hour for the first 6 doses on the first day, then the following day take 2 tablets 3 times a day until symptoms improve for up to a maximum of 7 days.

Tablets to be sucked or chewed and are to be taken between meals.

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

If the symptoms worsen, or do not improve after 7 days, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to Gelsemium sempervirens or any of the excipients.

4.4 Special warnings and precautions for use

Do not exceed the stated dose

If symptoms worsen, if fever (high temperature) is experienced, or if symptoms do not improve after 7 days, a doctor or qualified healthcare practitioner should be consulted.

This product is not recommended for use in children under 12 years of age and medical advice should be sought.

Contains lactose and sucrose - Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrose-insomaltese insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation: There is no evidence of the safety of the product in human pregnancy or lactation, nor is there any evidence from animal studies. Although no adverse events have been observed, the use of this product during pregnancy and lactation should be avoided unless under the guidance of a doctor.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

Studies on the effects on the ability to drive or use machinery have not been performed.

4.8 Undesirable effects

None known

If any adverse reactions occur, a doctor or pharmacist should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No reports

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Sucrose
Stearic acid
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium/PVC blister strips packed in a cardboard carton
Pack size: 72 tablets

6.6 Special precautions for disposal

There are no special precautions for disposal

7 MARKETING AUTHORISATION HOLDER

A Nelson & Co Limited
5-9 Endeavour Way
Wimbledon
London
SW19 8UH
UK

8 MARKETING AUTHORISATION NUMBER

HOA1149/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd of December 2016.

10 DATE OF REVISION OF THE TEXT