IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0030/022/001
Case No: 2061350

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Novartis Consumer Health UK Ltd

Wimblehurst Road, **Horsham**, **West Sussex RH12 5AB**, **England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Tixylix Chesty Cough

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **12/06/2009**.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tixylix Chesty Cough

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of solution contains 50mg of Guaifenesin as the active substance.

Each 5ml of solution also contains 1.14g of Sorbitol (E420).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution
A clear, almost colourless solution with a flavour of blackcurrant.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Symptomatic relief of chesty coughs.

Helps loosen mucus to make breathing easier.

4.2 Posology and method of administration

For children: The following doses are given 4 hourly.

Under 2 years	Do not use
2 – 5 years	5 ml
6 – 10 years	5 to 10ml

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

Guaifenesin containing products should not be taken with cough suppressants.

Do not exceed the stated dose.

Not more than 6 doses should be given in 24 hours.

It is recommended that if a child is under 6 years, a pharmacist or other healthcare professional should be consulted before the child is given Tixylix Chesty Cough.

It is recommended that Tixylix Chesty Cough should not be taken with any other cough and cold medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Not recommended with a cough suppressant.

4.6 Pregnancy and lactation

None.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

At the recommended dosage, none.

4.9 Overdose

Symptoms of very large overdose are nausea and vomiting. The drug is, however, rapidly metabolised and excreted in the urine. Patients should be kept under observation and treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Guaifenesin is reported to reduce the viscosity of tenacious sputum and is used as an expectorant.

5.2 Pharmacokinetic properties

Guaifenesin is readily absorbed from the gastrointestinal tract. It is readily metabolised and excreted in the urine.

It has a plasma half life of 1 hour.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Benzoate
Sodium Saccharin
Glycerol
Sorbitol solution (70%) (non-cryst)
Anhydrous Citric Acid or Citric Acid Monohydrate
Blackcurrant flavour (contains propylene glycol)
Vanilla flavour (contains propylene glycol)
Acesulfame Potassium
Hydroxyethylcellulose
Purified Water

6.2 Incompatibilities

None known.

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

100 ml amber glass bottle with a screw cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Novartis Consumer Health UK Limited
Trading as:
Novartis Consumer Health
Wimblehurst Road
Horsham
West Sussex
RH12 5AB
England

8 MARKETING AUTHORISATION NUMBER

PA 30/22/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 August 1996

Date of last renewal: 07 August 2006

10 DATE OF REVISION OF THE TEXT

August 2008