National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT
Novalyn Dry Cough Syrup (Adult Formula)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5ml contains Dextromethorphan Hydrobromide 15mg
For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM
Brown coloured liquid for oral administration.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
For the relief of persistent dry irritant coughs.

4.2 Posology and method of administration
Oral administration.

Adults, the elderly and children over 12 years: 5ml every 4 hours or 10ml every 6 to 8 hours to a maximum of 5 doses in 24 hours.

4.3 Contraindications
Hypersensitivity to any of the ingredients.
Taking a prescription monoamine oxidase inhibitor (MAOI), a selective serotonin reuptake inhibitor (SSRI), or other medications for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the medication. If you are not sure if your prescription medication contains one of these medicines, ask a doctor or pharmacist before taking this product. (See section 4.5).

4.4 Special warnings and precautions for use
Patients suffering from chronic cough as occurs with smoking, asthma or patients suffering from an acute asthma attack, or where cough is accompanied by excessive secretions should be advised to consult a Healthcare Professional before use.
Causes of chronic cough should be excluded if symptoms are persistent. Any accompanying symptoms should be actively sought and appropriately investigated/ treated. Stop use and ask your healthcare professional if your cough lasts more than 7 days, comes back or is accompanied by a fever, rash or persistent headache. These could be signs of serious conditions.
Cases of dextromethorphan abuse have been reported. Caution is particularly recommended for adolescents and young adults as well as in patients with a history of drug abuse or psychoactive substances.
Dextromethorphan is metabolised by hepatic cytochrome P450 2D6. The activity of this enzyme is genetically determined. About 10% of the general population are poor metabolizers of CYP2D6. Poor metabolizers and patients with concomitant use of CYP2D6 inhibitors may experience exaggerated and/or prolonged effects of dextromethorphan. Caution should therefore be exercised in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors (see also section 4.5).
Keep out of the sight and reach of children.
Do not exceed recommended dose.

Excipient warnings:
- This medicinal product contains 2.5% v/v ethanol (alcohol), up to 196 mg per dose, (equivalent to approx 1.6 ml wine per dose). Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women and high-risk groups such as patients with liver disease, or epilepsy.

4.5 Interaction with other medicinal products and other forms of interaction
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI), a selective serotonin reuptake inhibitor (SSRI), or other medications for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the medication. If you are not sure if your prescription medication contains one of these drugs, ask a doctor or pharmacist before taking this product.
CYP2D6 inhibitors
Dextromethorphan is metabolized by CYP2D6 and has an extensive first-pass metabolism. Concomitant use of potent CYP2D6 enzyme inhibitors can increase the dextromethorphan concentrations in the body to levels multifold higher than normal. This increases the patient's risk for toxic effects of dextromethorphan (agitation, confusion, tremor, insomnia, diarrhoea and respiratory depression) and development of serotonin syndrome.
Potent CYP2D6 enzyme inhibitors include fluoxetine, paroxetine, quinidine and terbinafine. In concomitant use with quinidine, plasma concentrations of dextromethorphan have increased up to 20-fold, which has increased the CNS adverse effects of the agent.
Amiodarone, flecainide and propafenone, sertraline, bupropion, methadone, cinacalcet, haloperidol, perphenazine and thioridazine also have similar effects on the metabolism of dextromethorphan. If concomitant use of CYP2D6 inhibitors and dextromethorphan is necessary, the patient should be monitored and the dextromethorphan dose may need to be reduced.

4.6 Pregnancy and lactation
Although dextromethorphan has been in widespread use for many years without apparent ill-consequence, there are no specific data on its use during pregnancy. Caution should therefore be exercised by balancing the potential benefit of treatment against any possible hazards. It is not known whether dextromethorphan or its metabolites are excreted in human milk.

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. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When taking this medicine, patients should be told:
• The medicine is likely to affect your ability to drive
• Do not drive until you know how the medicine affects you
• It is an offence to drive while under the influence of this medicine
• However, you would not be committing an offence (called 'statutory defence') if:
o The medicine has been prescribed taken to treat a medical problem and
o You have taken it according to the information provided with the medicine and
o It was not affecting your ability to drive safely

4.8 Undesirable effects
Adverse effects are rare, however the following side effects may be associated with dextromethorphan hydrobromide:
Gastrointestinal Disorders
Rare: Gastrointestinal upset
Nervous System Disorders
Rare: Dizziness, drowsiness, mental confusion
Immune System Disorders
Hypersensitivity

4.9 Overdose
Symptoms:
These include nausea and vomiting, CNS depression, dizziness, dysarthria (slurred speech), myoclonus, nystagmus, somnolence (drowsiness), tremor, excitation, mental confusion, psychotic disorder (psychosis), and respiratory depression.

Management:
Treatment of overdose should be symptomatic and supportive. Gastric lavage may be of use. Naloxone has been used successfully as a specific antagonist to dextromethorphan toxicity in children.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dextromethorphan hydrobromide is a cough suppressant which has a central action on the cough centre in the medulla. It has no analgesic properties and little sedative activity.
Dextromethorphan
Pharmacotherapeutic group: Cough suppressant
ATC code: R05DA09

5.2 Pharmacokinetic properties

Dextromethorphan hydrobromide is well absorbed from the gastrointestinal tract.
Dextromethorphan undergoes rapid and extensive first-pass metabolism in the liver after oral administration. Genetically controlled O-demethylation (CYD2D6) is the main determinant of dextromethorphan pharmacokinetics in human volunteers.
It appears that there are distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects. Unmetabolised dextromethorphan, together with the three demethylated morphinan metabolites dextrorphan (also known as 3-hydroxy-N-methylmorphinan), 3-hydroxymorphinan and 3-methoxymorphinan have been identified as conjugated products in the urine. Dextrorphan, which also has antitussive action, is the main metabolite. In some individuals metabolism proceeds more slowly and unchanged dextromethorphan predominates in the blood and urine.

5.3 Preclinical safety data

There is no relevant information additional to that already contained elsewhere in the SmPC or of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Glycerol
Sodium Benzoate
Ethanol 96%
Sucrose
Aspartame
Citric Acid Anhydrous
Sodium Citrate
Sorbitol Solution 70% (Non-crystallizing)
Sodium Carboxymethyl Cellulose
Caramel
Menthol Crystals
Raspberry Flavour
Deionised Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C.
Keep out of reach and sight of children.

6.5 Nature and contents of container
PET bottles containing 100ml with Aluminium ROPP screw caps.
A clear polypropylene measuring cup also included.

6.6 Special precautions for disposal and other handling
No special requirements

7. APPLICANT/MANUFACTURER
SKG-Pharma Limited
7/9 Sapara Street,
Ikeja, Lagos State, Nigeria.
Tel: +234(1)44544640
Email: skgpharma@yahoo.com