**SUMMARYOFPRODUCTCHARACTERISTICS**

# NAME OF THEMEDICINAL PRODUCT

# <TRADE NAME> <STRENGTH> Lozenges

# <REGARDING TE APPROVAL>

# QUALITATIVEANDQUANTITATIVECOMPOSITION

# Each Lozenges contains <STRENGTH> <GENERIC NAME>

# Excipient with known effect:

# <REGARDING THE APPROVAL>

# For the full list of excipients, see section 6.1.

1. **PHARMACEUTICAL FORM**

Lozenge

<REGARDING THE APPROVAL>

# CLINICALPARTICULARS

# Therapeutic indications

# Cough suppressant for the relief of acute non-productive (dry, tickly) cough associated with respiratory tract infection.

# For oral administration.

## Posology and method of administration

## Adults and children over 12 years: A lozenge should be sucked whenever the cough is troublesome. Not more than 10 lozenges should be taken in one day.

## The normal adult dose is still appropriate in the elderly.

## Children 6 to 12 years: Not more than 2 lozenges within any 4 hours, and not more than 7 in any one day.

## Not to be used for more than 5 days without the advice of a doctor. Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

## This medicine is contraindicated in children under 6 years of age (see section 4.3).

## Warning: Do not exceed the stated dose.

## Keep all medicines out of the sight and reach of children.

## Contraindications

## Hypersensitivity to the active substance or any of the excipients.

## <GENERIC NAME> should not be given to subjects in, or at risk of developing respiratory failure.

## Should not be taken by patients with liver disease.

## Patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment (see also section 4.5).

## Patients taking selective serotonin reuptake inhibitors (SSRI's, see section 4.5).

## Not to be used in children under the age of 6 years

## Special warnings and precautions for use

## Should be used with caution in atopic children due to histamine release.

## Ask a doctor before use if you suffer from a chronic or persistent cough, if you have asthma or are suffering from an acute asthma attack or where cough is accompanied by excessive secretions.

## Do not take with any other cough and cold medicine.

## Use of <GENERIC NAME> with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.

## Drug dependence, tolerance and potential for abuse

## For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression)

## Drug withdrawal syndrome

## The drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.

## <GENERIC NAME> is metabolised by hepatic cytochrome P450 2D6. The activity of this enzyme is genetically determined. About 10% of the general population are poor metabolisers of CYP2D6. Poor metabolisers and patients with concomitant use of CYP2D6 inhibitors may experience exaggerated and/or prolonged effects of <GENERIC NAME>. Caution should therefore be exercised in patients who are slow metabolisers of CYP2D6 or use CYP2D6 inhibitors (see also section 4.5).

## If symptoms do not go away talk to your doctor.

## Serotonin Syndrome

## Serotonergic effects, including the development of a potentially lifethreatening serotonin syndrome, have been reported for <GENERIC NAME> with concomitant administration of serotonergic agents, such as selective serotonin re-uptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including monoamine oxidase inhibitors (MAOIs)) and CYP2D6 inhibitors.

## Serotonin syndrome may include mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms.

## If serotonin syndrome is suspected, treatment with <TRADE NAME> Lozenges should be discontinued.

## Paediatric population

## Serious adverse events may occur in children in case of overdose including neurological disorders. Caregivers should be advised not to exceed the recommended dose.

## Interaction with other medicinal products and other forms of interaction

## Not to be used in patients taking monoamine oxidase inhibitors or within 14 days of stopping treatment as there is a risk of serotonin syndrome (pyrexia, hypertension, arrhythmias) when MAOIs are taken in combination with <GENERIC NAME>.

Severe and sometimes fatal reactions have been reported following administration of <GENERIC NAME> to patients receiving MAOIs (see also section 4.3).

<GENERIC NAME> might exhibit additive CNS depressant effects when coadministered with alcohol, antihistamines, psychotropics, and other CNS depressant drugs.

CYP2D6 inhibitors

<GENERIC NAME> is metabolized by CYP2D6 and has an extensive first-pass metabolism. Concomitant use of potent CYP2D6 enzyme inhibitors can increase the <GENERIC NAME> concentrations in the body to levels multifold higher than normal. This increases the patient’s risk for toxic effects of <GENERIC NAME> (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 <GENERIC NAME> have increased up to 20-fold, which has increased the CNS adverse effects of the agent. Amiodarone, flecaninde and propafenone, sertraline, bupropion, methadone, cinacalcet, haloperidol, perphenazine and thioridazine also have similar effects on the metabolism of <GENERIC NAME>. If concomitant use of CYP2D6 inhibitors and <GENERIC NAME> is necessary, the patient should be monitored and the <GENERIC NAME> dose may need to be reduced.

## Fertility, pregnancy and lactation

## There is no or inadequate evidence of the safety of <GENERIC NAME> in human pregnancy and therefore the lozenges should not be used during this period. No information is available on the secretion of <GENERIC NAME> into breast milk and it is recommended that the product should not be used by breast feeding mothers.

## 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 <REGARDING TE APPROVAL>. When prescribing 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 a ‘statutory defence’) if:
	+ The medicine has been prescribed to treat a medical or dental problem and
	+ You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
	+ It was not affecting your ability to drive safely

## Undesirable effects

## The following side effects may be associated with the use of <GENERIC NAME>; occasional drowsiness, dizziness, excitation, mental confusion, convulsions, respiratory depression, vomiting, gastrointestinal disturbances (nausea and diarrhoea) and skin reactions including rash.

## Psychiatric disorders:

## Frequency unknown: Drug dependence (see section 4.4)

## General disorders and administration site conditions:

## Frequency unknown: drug withdrawal syndrome

## Overdose

## The effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

## Symptoms and signs:

## <GENERIC NAME> overdose may be associated with nausea, vomiting, dystonia, agitation, confusion, somnolence, stupor, nystagmus, cardiotoxicity (tachycardia, abnormal ECG including QTc prolongation), ataxia, toxic psychosis with visual hallucinations, hyperexcitability. Other observed symptoms include CNS depression. Dizziness, dysarthria (slurred speech), abdominal discomfort and hypotension.

## In the event of massive overdose the following symptoms may be observed: coma, respiratory depression, convulsions.

## Management:

* Activated charcoal can be administered to asymptomatic patients who have ingested overdoses of <GENERIC NAME> within the preceding hour.
* For patients who have ingested <GENERIC NAME> and are sedated or comatose, naloxone, in the usual doses for treatment of opioid overdose, can be considered. -Benzodiazepines for seizures and benzodiazepines and external cooling measures for hyperthermia from serotonin syndrome can be used.
* Treatment of overdose should be symptomatic and supportive. Gastric lavage may be of use.

Information regarding children aged 6-12 years:

Naloxone has been used successfully to reverse central or peripheral opioid effects of <GENERIC NAME> in children (0.01mg/kg body weight).

## PHARMACOLOGICAL PROPERTIES

## Pharmacodynamic Properties

## <GENERIC NAME> is a cough suppressant.

### Pharmacokinetic properties

### <GENERIC NAME> is well-absorbed from the gastrointestinal tract, metabolised in the liver and excreted as both unchanged drug and demethylated metabolites.

### <GENERIC NAME> undergoes rapid and extensive first-pass metabolism in the liver after oral administration. Genetically controlled O-demethylation (CYD2D6) is the main determinant of <GENERIC NAME> pharmacokinetics in human volunteers.

### It appears that there are distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects. Unmetabolised <GENERIC NAME>, together with the three demethylated morphinan metabolites dextrorphan (also known as 3-hydroxy-N-methylmorphinan), 3hydroxymorphinan 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 <GENERIC NAME> predominated in the blood and urine.

### Pre-clinical Safety Data

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

## PHARMACEUTICAL PARTICULARS

## List of Excipients

## <REGARDING THE APPROVAL>

* 1. **Incompatibilities**

<REGARDING THE APPROVAL>

* 1. **Shelf life**

<REGARDING THE APPROVAL>

* 1. **Special precautions for storage**

<REGARDING THE APPROVAL>

* 1. **Nature and contents of container**

## <REGARDING THE APPROVAL>

* 1. **Special precautions for disposal**

<REGARDING THE APPROVAL>

1. **MARKETING AUTHORISATION HOLDER**

<REGARDING THE APPROVAL>

### MARKETING AUTHORISATION NUMBER

### <REGARDING THE APPROVAL>

1. **DATE OF FIRST AUTHORISATION / RENEWAL OF THE**

**AUTHORISATION**

<REGARDING THE APPROVAL>

# DATEOFREVISIONOFTHETEXT[[1]](#footnote-1)

# <REGARDING THE APPROVAL>

1. Ref: Dextromethorphan , MHRA, 21/04/2020 [↑](#footnote-ref-1)