

## BISOLVON® DRY ORAL LIQUID

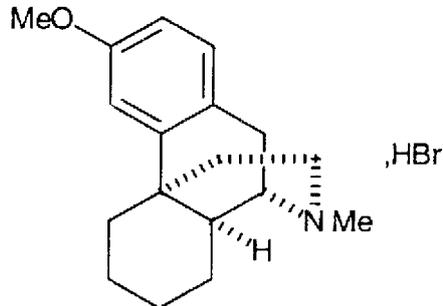
### PRODUCT INFORMATION

#### DESCRIPTION

**Approved Name** Dextromethorphan hydrobromide

**Chemical Name** (9S,13S,14S)-6,18-dideoxy-7,8-dihydro-3-O-methylmorphine  
C<sub>18</sub>H<sub>25</sub>NO, HBr  
CAS number: 125-69-9

Dextromethorphan hydrobromide is a white or almost white crystalline powder, soluble in alcohol and chloroform, sparingly soluble in water, and practically insoluble in ether. The structural formula for dextromethorphan hydrobromide is as follows:



Bisolvon Dry is a liquid preparation for oral administration. Each 5 mL of Bisolvon Dry contains dextromethorphan hydrobromide 10 mg. Other ingredients include methyl hydroxybenzoate, saccharin sodium, maltitol solution, propylene glycol, vanilla aroma 33P080, apricot aroma 653460, and purified water.

#### PHARMACOLOGY

Dextromethorphan is an opioid antitussive substance that exerts a depressant action on the medullary cough centre, thereby elevating the cough threshold. It does not possess analgesic, respiratory-suppressant or psychomimetic properties in therapeutic doses.

The onset of effect occurs within an hour after oral administration and the duration of effect is approximately 3 – 6 hours.

## **Pharmacokinetics**

Dextromethorphan hydrobromide is rapidly absorbed after oral administration and peak plasma levels are reached within 2 hours. Dextromethorphan hydrobromide is metabolised in the liver via a first pass effect. The principal stages of metabolism are oxidative O- and N-demethylation with subsequent conjugation. The primary active metabolite is dextorphan; (+)-3-methoxymorphinan and (+)-3-hydroxymorphinan are also formed. The rate of polymorphism during oxidative metabolism (debrisoquine-type) is 5 -10%. The renally excreted proportion (up to 48 hours after oral administration) can range from 20 to 86% of the administered dose. Free or conjugated metabolites are recovered in the urine and only a small proportion of the active ingredient is eliminated in an unchanged form. Less than 1% is found in the faeces.

The plasma elimination half-life is 1.2 – 2.2 hours, extending to as much as 45 hours if abnormal metabolism is involved (polymorphism).

## **INDICATIONS**

Bisolvon Dry is used for the symptomatic treatment of dry, irritant, unproductive coughs.

## **CONTRAINDICATIONS**

Bisolvon Dry is contraindicated in asthma, chronic obstructive airways disease, pneumonia, respiratory failure, respiratory depression, during lactation and in cases of hypersensitivity to dextromethorphan or any excipient of the product.

## **PRECAUTIONS**

Do not use Bisolvon Dry in children under 2 years of age.

If the cough persists for more than 1 week, a doctor should be consulted for further diagnostic clarification.

In cases of productive cough with considerable mucus production, antitussive treatment with Bisolvon Dry should be administered with particular caution and only after medical advice.

Bisolvon Dry should be used with caution in patients with impaired liver function or who are receiving a monoamine oxidase inhibitor antidepressant; in case of doubt, these patients should ask for medical advice.

Patients with fructose intolerance should not receive Bisolvon Dry.

### **Use in pregnancy**

Category A: Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

Experimental studies with dextromethorphan hydrobromide and observations in humans have not shown harmful effects on reproduction or on foetal development.

Because animal studies are not always predictive of human response, Bisolvon Dry should not be used in the first three months of pregnancy; in later pregnancy periods it should only be taken if clearly needed.

### **Use in lactation**

The extent of excretion in breast milk is not known; therefore, the use of Bisolvon Dry is contraindicated during lactation.

### **Interactions with other drugs**

Concomitant treatment with MAO-inhibitors may cause effects on the central nervous system, e.g. excitation, high fever and changes in respiratory and/or circulatory functions.

The concomitant administration of other medicines with a suppressant effect on the central nervous system or the consumption of alcohol may lead to mutual potentiation.

Serum levels of dextromethorphan may be increased by the concomitant use of the antiarrhythmics quinidine and amiodarone, and the antidepressants fluoxetine, fluvoxamine and paroxetine.

## **ADVERSE EFFECTS**

In general, undesirable effects at recommended dosages are rare.

Drowsiness, dizziness, nausea, vomiting, reduction of appetite, gastrointestinal disorders and hypersensitivity reactions may occur.

Even if taken in recommended doses, the ability to drive or operate machinery may be impaired, especially in association with the intake of alcohol or other medicines which can impair reaction times themselves.

Cases of dextromethorphan abuse and dependency have been reported.

Bisolvon Dry contains at least 3 g of maltitol and up to 1 g of sorbitol in 10 mL, which may have a laxative effect or cause diarrhoea in some people. This is more likely if several products containing maltitol, sorbitol or other related substances are consumed simultaneously.

## **DOSAGE AND ADMINISTRATION**

The following dosage regimen is recommended:

### **Bisolvon Dry:**

#### Adults and adolescents over 12 years:

5 – 15 mL of Bisolvon Dry, every 4 – 6 hours when necessary.

The maximum total daily dose is 60 mL of Bisolvon Dry (equivalent to 120 mg dextromethorphan hydrobromide). Do not exceed 4 doses in a 24 hour period.

#### Children 6 – 12 years:

2.5 – 7.5 mL of Bisolvon Dry, every 4 – 6 hours when necessary.

The maximum total daily dose is 30 mL of Bisolvon Dry (equivalent to 60 mg of dextromethorphan hydrobromide). Do not exceed 4 doses in a 24 hour period.

#### Children 2 – 6 years:

1.25 – 3.75 mL of Bisolvon Dry, every 4 – 6 hours when necessary.

The maximum total daily dose is 15 mL of Bisolvon Dry (equivalent to 30 mg of dextromethorphan hydrobromide). Do not exceed 4 doses in a 24 hour period.

#### Children under 2 years:

Bisolvon Dry should not be used.

If the cough persists for more than 1 week, a doctor should be consulted for further diagnostic clarification.

## **OVERDOSAGE**

In case of overdose, immediately contact the Poisons Information Centre (call 13 11 26) for advice.

## Symptoms

The effects of an overdose include nausea, vomiting, vision impairment and CNS-disorders like ataxia. Dizziness, excitation, increased muscle tonus, impaired consciousness, drop in blood pressure and tachycardia may occur.

In extreme cases, urinary retention and respiratory depression may ensue.

## Therapy

If necessary initiate intensive medical measures (in particular intubation, ventilation).

Measures to guard against heat loss and volume replacement may also prove necessary. The intravenous administration of naloxone may antagonise the central nervous effects of dextromethorphan.

Do not administer central acting emetics.

## **PRESENTATION**

Bisolvon Dry is a clear, colourless, syrupy liquid with an aroma of apricot and vanilla, available in amber-coloured bottles containing 125 mL and 200 mL. Each 5 mL contains 10 mg dextromethorphan hydrobromide.

Bisolvon Dry should be stored below 30°C and protected from direct sunlight.

## **POISONS SCHEDULE**

S2

## **NAME AND ADDRESS OF SPONSOR**

Boehringer Ingelheim Pty Limited  
ABN 52 000 452 308  
78 Waterloo Road  
North Ryde NSW 2113

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