

## **1. NAME OF THE MEDICINAL PRODUCT**

Dihydrocodeine 30mg tablets.

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Dihydrocodeine Tartrate BP 30.0 mg.

## **3. PHARMACEUTICAL FORM**

Tablet.

## **4. CLINICAL PARTICULARS**

### **4.1. Therapeutic Indications**

For moderate to severe pain.

### **4.2. Posology and Method of Administration**

Adults: One tablet every 4-6 hours when necessary after food. Maximum dose in 24 hours 180mg (6 tablets).

Not recommended for children under 12 years.

Dosage should be reduced for the elderly.

For oral administration.

### **4.3. Contra-Indications**

Respiratory depression; obstructive airways disease; hypersensitivity to the product.

### **4.4 Special warnings and precautions for use**

MAOIs should not be given with the dihydrocodeine or other narcotic analgesics. MAOIs should be stopped for at least two to three weeks before dihydrocodeine treatment is initiated. Do not give during an attack of asthma, and administer with caution to patients liable to such attacks. The dosage should be reduced in the elderly, in hypothyroidism, in chronic hepatic disease and in renal insufficiency. Alcohol should be avoided during treatment with dihydrocodeine. The risk-benefit of continued use should be assessed regularly by the prescriber.

### **4.5. Interactions with other Medicinal Products and other Forms of Interaction**

Dihydrocodeine tartrate causes delayed absorption of mexiletine, potentiates the action of hypnotics and sedatives, causes CNS excitation and hypertension by interaction with MAOIs. Opioid analgesics should be avoided in patients with raised intracranial pressure or head injury.

### **4.6. Pregnancy and Lactation**

Inadequate evidence of safety in human pregnancy, but the drug has been used for many years without apparent ill consequence. There is no evidence of excretion in human milk, but dihydrocodeine should only be administered to breast-feeding mothers if considered essential.

### **4.7. Effects on Ability to Drive and Use Machines**

Dihydrocodeine may cause drowsiness and if patients are affected they should not drive or operate machinery.

### **4.8 Undesirable effects**

Constipation, nausea, vomiting, urinary retention, headache and vertigo. May cause dependence. Side effects are more common when the dose exceeds 30mg. Regular prolonged use of codeine/DHC is known to lead to addiction and symptoms of restlessness

and irritability may result when treatment is then stopped. Prolonged use of a pain killer for headaches can make them worse

#### **4.9. Overdose**

Gastric lavage should be carried out. If severe respiratory depression occurs appropriate supportive treatment for respiratory and cardiovascular symptoms including hospitalization should be instituted. Severe respiratory depression should be treated with naloxone hydrochloride 0.8mg to 2mg intravenously, repeated as required or at 2-3 minute intervals, up to a maximum of 10mg.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1. Pharmacodynamic Properties**

Dihydrocodeine tartrate is a potent analgesic with well defined anti-tussive properties

#### **5.2. Pharmacokinetic Properties**

The pharmacokinetics of dihydrocodeine may be similar to those of codeine; they differ between subjects with normal renal function and those with chronic renal failure treated with haemodialysis. Dihydrocodeine is well absorbed from the gastrointestinal tract following oral administration, and a small quantity is bound to plasma proteins. Peak levels of plasma dihydrocodeine concentration are attained in an hour following ingestion. Plasma half-life has been reported to be 34 hours after oral ingestion. Dihydrocodeine is metabolised in the liver by O- and N- demethylation. Dihydrocodeine and its metabolites are excreted entirely by the kidneys mainly as conjugates with glucuronic acid.

#### **5.3. Pre-clinical Safety Data**

Not applicable

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1. List of Excipients**

Starch, povidone (K= 29/32), Lactose, Sodium starch glycollate, Magnesium stearate, Colloidal.

#### **6.2. Incompatibilities**

None stated.

#### **6.3. Shelf-Life**

3 years

#### **6.4. Special Precautions for Storage**

Store in a cool dry place protected from light below 25°C.

#### **6.5. Nature and Content of Container**

Securitainers containing 25, 50, 100, 250, 500 or 1000 tablets.  
Blister packs in cartons of 28 or 30 tablets

#### **6.6. Instruction for Use, Handling and Disposal**

Not applicable.

### **7. MARKETING AUTHORISATION HOLDER**

Forley Generics Limited  
NLA tower  
12-16 Addiscombe Road  
Croydon  
CR0 0XT  
United Kingdom.

**8. MARKETING AUTHORISATION NUMBER**

PL 16201/0007

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION**

22 July 1999.

**10 DATE OF REVISION OF THE TEXT**

04/01/2011