

# HEXAPNEUMINE® INFANTS

## Syrup

### IDENTIFICATION OF THE MEDICINAL PRODUCT

#### COMPOSITION

Biclotymol ..... 0.100 g  
Chlorphenamine maleate ..... 0.005 g  
Excipients : Tolu balsam, alcohol, orange yellow S, saccharose, guar gum, sodium methyl parahydroxybenzoate (E219), citric acid monohydrate, sodium citrate, orange flavouring, purified water. For 100 ml of syrup.

#### PHARMACEUTICAL FORM

Syrup, 100 ml bottle.

#### PHARMACO-THERAPEUTIC GROUP

ANTIHISTAMINE FOR SYSTEMIC USE

(R : respiratory system).

#### NAME AND ADDRESS OF THE MARKETING COMPANY

BOUCHARA-RECORDATI Laboratories  
68 Rue Marjolin  
92 300 LEVALLOIS-PERRET - France

#### WHEN TO USE THIS MEDICINE?

This medicine contains an antihistamine, chlorpheniramine.

It is recommended to soothe dry coughs and irritant coughs which occur particularly in the evening or during the night in infants up to the age of 30 months.

#### WARNING!

##### WHEN NOT TO USE THIS MEDICINE?

This medicine MUST NOT BE USED in the following cases :

- allergy to any of the ingredients,
- difficulty in urinating,
- certain forms of glaucoma (increase in pressure in the eye).

*IF IN DOUBT, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.*

#### SPECIAL WARNINGS

It is necessary to consult a doctor if a new-born child develops a cough.

- Do not use this medicine to treat a productive cough. In this case, the cough is a natural defence mechanism which is necessary for the evacuation of bronchial secretions.
- If the cough becomes productive accompanied by congestion, sputum or fever, ask your doctor for advice.
- Medical advice is necessary if your child suffers from chronic (long-term) illness affecting the bronchial tubes or the lungs accompanied by coughing with sputum.
- It is not advisable to combine this cough remedy with a medicine which loosens bronchial secretions (expectorant, mucolytic).

#### WARNING : THIS MEDICINE CONTAINS ALCOHOL

The alcohol content of the syrup is 2.5 %, i.e.  
49.5 mg of alcohol per 2.5 ml spoonful

#### SPECIAL PRECAUTIONS FOR USE

If your child suffers from long-term liver or kidney disease, CONSULT YOUR DOCTOR so that he/she can adapt the dosage.

MEDICAL ADVICE is required when taking this medicine if your child suffers from asthma or a gastro-oesophageal reflux, NOTIFY YOUR DOCTOR before giving this medicine to your child.

Do not use this treatment in combination with other medicines which contain alcohol.

If your child is diabetic or on a low-sugar diet, bear in mind the sugar content of the daily intake : 1.875 g per 2.5 ml spoonful.

*IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE*

#### INTERACTIONS WITH OTHER MEDICINES AND OTHER INTERACTIONS

*YOU MUST TELL YOUR DOCTOR OR PHARMACIST IF YOUR CHILD IS TAKING ANY OTHER TREATMENTS IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN DIFFERENT DRUGS.*

*This medicine contains an antihistamine, chlorpheniramine. This is also found in other medicines. Do not use them in combination with other medicines, so that you do not exceed the maximum recommended dose (see dosage and method of administration)*

#### LIST OF EXCIPIENTS WHICH NEED TO BE KNOWN FOR SAFE USE IN CERTAIN PATIENTS

Saccharose (1.875 g/spoonful), alcohol (49.5 mg/spoonful) and sodium methylparahydroxybenzoate (E219).

#### HOW TO USE THIS MEDICINE?

##### DOSAGE

FOR INFANTS ONLY (up to the age of 30 months)

You must consult your doctor if your infant develops a cough.

Use the 2.5 ml measuring spoon given with this syrup and follow the prescription from your doctor. For information purposes : two to six 2.5 ml spoonfuls to be taken at intervals throughout the day.

Wash the measuring spoon after use.

*THIS MEDICINE HAS BEEN PRESCRIBED FOR YOUR PERSONAL USE IN A SPECIFIC SITUATION :*

- IT MAY NOT BE SUITABLE FOR OTHER SITUATIONS
- DO NOT RECOMMEND IT TO ANYONE ELSE.

#### METHOD AND ROUTE OF ADMINISTRATION

ORAL ROUTE.

#### WHEN AND HOW OFTEN TO TAKE YOUR MEDICINE

The doses should be taken at intervals of at least 4 hours.

#### DURATION OF TREATMENT

The duration of the treatment must be short (several days) and restricted to times when the cough occurs.

#### WHAT TO DO IF AN OVERDOSE IS TAKEN

Consult a doctor.

#### UNDESIRABLE AND UNPLEASANT EFFECTS

AS WITH ALL ACTIVE PRODUCTS, THIS MEDICINE CAN CAUSE UNPLEASANT EFFECTS OF VARYING SEVERITY IN SOME PEOPLE

Certain effects make it necessary TO STOP THE TREATMENT IMMEDIATELY and NOTIFY a doctor :

- Allergic reactions :

- such as skin rash (erythema, eczema, purpura, urticaria),
- Quincke oedema (urticaria with rapid swelling of the face and neck which may lead to respiratory problems),
- anaphylactic shock,
- Significant decrease in white blood cell count revealed by the onset or worsening of fever, possibly accompanied by signs of infection,
- Abnormal decrease in platelets in the blood revealed by nosebleeds or bleeding gums.

Others are more common :

- Drowsiness, decreased alertness which is more pronounced at the start of treatment,
- Decrease in concentration, dizziness,
- Lack of motor coordination, trembling,
- Confusion, hallucination,
- Dryness of the mouth, visual disturbance, retention of urine, constipation, palpitations, decrease in blood pressure.

Signs of excitation (agitation, nervousness, insomnia) are rarer, but may occur, particularly in infants.

*TELL YOUR DOCTOR IF YOU EXPERIENCE ANY UNWANTED OR UNPLEASANT EFFECTS WHICH ARE NOT MENTIONED IN THIS LEAFLET.*

#### STORAGE

DO NOT USE AFTER THE EXPIRY DATE STATED ON THE OUTER PACKAGING

#### DATE OF REVISION OF THE INFORMATION LEAFLET

September 2004.



Les laboratoires BOUCHARA-RECORDATI participent à CYCLAMED, association chargée de la collecte et de l'élimination des déchets issus de médicaments. Ils vous demandent en conséquence de rapporter à votre pharmacien l'emballage de ce médicament vide ou non.