

HEXAPNEUMINE® ADULTS

Syrup

IDENTIFICATION OF THE MEDICINAL PRODUCT

COMPOSITION

Pholcodine 0.120 g
Chlorphenamine maleate 0.012 g
Biclotymol 0.200 g
Excipients: Alcohol, orange yellow S, saccharose, guar gum, sodium methylparahydroxybenzoate (E219), citric acid monohydrate, sodium citrate, orange flavour, purified water. For 100 ml syrup.

PHARMACEUTICAL FORM

Syrup, bottle of 200 ml.

PHARMACO-THERAPEUTIC GROUP

ANTITUSSIVE - 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 antitussive agent (pholcodine) and an anti-histaminic (**chlorphenamine**).

This medicine is recommended for the symptomatic treatment of dry coughs and tickly coughs in adults and children aged over 15 years in particular during the night.

WARNING!

WHEN NOT TO USE THIS MEDICINE?

This medicine MUST NOT BE USED in the following situations:

- an allergy to one of the ingredients,
- children aged below 15 years,
- an asthmatic cough,
- respiratory insufficiency,
- prostatic troubles or **deficiency** of the urinary tract,
- certain forms of glaucoma,
- breast-feeding.

IF IN DOUBT, YOU MUST ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

SPECIAL WARNINGS

WARNING : the alcoholic degree is 6.8% i.e. 270 mg of alcohol in a tea-spoon.

Do not treat a chesty cough with this medicine. Chesty coughs are a natural means of defence which are necessary to clear bronchial secretions.

Seek the advice of your doctor if the cough becomes chesty and is accompanied by congestion, production of sputum and fever.

In the case of a chronic (long term) bronchial or lung disorder accompanied by production of sputum, you must seek medical advice.

Do not combine to an agent to fluidify the bronchial secretions (i.e. expectorants or mucolytic agents), you must seek medical advice.

PRECAUTIONS FOR USE

In the case of a chronic liver or renal disorder, INFORM YOUR DOCTOR to adapt the dosage.

Taking this drug needs a medical advice if you are an elderly person :

- suffering from constipation, drowsiness and dizziness,
- presenting prostatic troubles.

INFORM YOUR DOCTOR before taking this medicine.

You are advised not to consume alcohol or medicines containing alcohol when taking this treatment.

In case of diabet or poor sugar diet, take into account the amount of sugar (3.75 g per tea-spoon).

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

INTERACTIONS WITH OTHER MEDICINES AND OTHER INTERACTIONS

TO PREVENT POSSIBLE INTERACTIONS BETWEEN DIFFERENT MEDICINES, ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER MEDICINE WHICH YOU ARE TAKING.

This medicine contains an antitussive, pholcodine and an anti-histaminic agent, chlorphenamine. Other medicines may contain them or another antitussive.

Do not combine them in order to avoid exceeding the maximum recommended doses (see dosage and method of administration).

PREGNANCY AND BREAST-FEEDING

PREGNANCY

You are advised not to use this medicine during pregnancy. If you discover that you are pregnant during treatment, notify your doctor as quickly as possible. Only your doctor will be able to

adjust the treatment to suit your condition.

BREAST-FEEDING

Pholcodine passes into breast milk.

Very high doses of codeine (a substance which is very similar to *pholcodine*) administered to women who are breast-feeding, may cause respiratory arrest or a reduction in the tone of the infant. In the case of breast-feeding, as with codeine, the administration of this medicine is **contra-indicated**.

In general, you should always seek the advice of your doctor or pharmacist before taking a medicine if you are pregnant or breast-feeding.

DRIVING AND OPERATING MACHINERY

Attention is drawn to the risk of drowsiness associated with the use of this medicine, particularly in people who drive or operate machinery.

The consumption of alcohol or medicines containing alcohol increase this effect.

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

Alcohol, saccharose and sodium methylparahydroxybenzoate (E219).

HOW TO USE THIS MEDICINE?

DOSAGE

This medicine must only be used by adults and children aged over 15 years.

If the medicine does not have the required effect, consult your doctor. Do not exceed the recommended dose and do not use it in combination with an antitussive.

The standard dose is:

- in adults: 2 tea-spoons per dose, to be repeated if necessary after 4 hours, without exceeding 6 doses in one day.
- in elderly subjects or in cases of hepatic or renal insufficiency: consult your doctor so that the dose can be adjusted.

METHOD AND ROUTE OF ADMINISTRATION

Oral route.

WHEN AND HOW OFTEN TO TAKE THIS MEDICINE

To be taken at 4 hour intervals.

DURATION OF TREATMENT

The treatment should be taken over a short period of time (a few days) and should be only taken at times when you have a cough.

WHAT TO DO IF AN OVERDOSE IS TAKEN

Consult a doctor.

UNDESIRABLE AND UNPLEASANT EFFECTS

THIS MEDICINE MAY PRODUCE UNPLEASANT EFFECTS OF VARYING SEVERITY IN SOME PEOPLE.

Some of the side-effects need TO STOP IMMEDIATELY THE TREATMENT and to inform your doctor:

Allergic reactions :

- cutaneous eruptions (erythema, eczema, purpura, urticaria),
- Quincke oedema (urticaria with brutal oedema of the face and the neck, that may provoke respiratory difficulties),
- anaphylactic shock.

Important decrease in the white blood cells count, that is signed by a appearance of fever or increase of this pre-existing fever, with or without infectious symptoms.

Anormal decrease of platelets in the blood, with nose or gum bleedings.

Others are more frequent :

- **drowsiness, decrease of vigilance**,
- respiratory difficulties (decrease of bronchial volume),
- memory and concentration troubles, vertigo (more frequent in elderly),
- reduced motor coordination, trembling,
- mental confusion, hallucinations,
- dryness of mouth, accommodation disturbances, risk of urinary retention, constipation, cardiac palpitations, decrease of blood pressure.
- nausea, vomiting.

More rarely: sign of excitation (agitation, nervousness, insomnia) may occur.

TELL YOUR DOCTOR OR PHARMACIST ABOUT ANY UNWANTED OR UNPLEASANT EFFECT WHICH IS NOT MENTIONED IN THIS INFORMATION 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.