



# Euphon<sup>®</sup>

## Syrup

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse.

### What is in this leaflet:

1. What EUPHON syrup is and what it is used for
2. What you need to know before you take EUPHON syrup
3. How to take EUPHON syrup
4. Possible side effects
5. How to store EUPHON syrup
6. Other information

### 1. WHAT EUPHON SYRUP IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Cough suppressant. ATC code R05D

This medicine contains a cough suppressant (codeine). This medicine is recommended for soothing dry coughs and irritating coughs in adults and children over the age of 12. You must talk to your doctor if you do not feel better or if you feel worse.

### 2. WHAT DO YOU NEED TO KNOW BEFORE YOU TAKE EUPHON SYRUP

#### Do not take EUPHON syrup:

- if you are allergic (hypersensitive) to the active substances or any of the other ingredients of this medicine listed in section 6.
- respiratory failure,
- asthmatic cough
- children under 12.
- if you know that your body metabolises codeine into morphine very rapidly.
- if you are breast-feeding.

Due to the presence of codeine, EUPHON syrup is not recommended for adolescents over the age of 12 with impaired respiratory function.

This medicine SHOULD NOT GENERALLY BE USED in combination with alcohol.

CHECK WITH YOUR DOCTOR OR PHARMACIST IF YOU ARE NOT SURE.

#### Warnings and precautions

**Warning!** The alcohol content of this syrup is 2.7 vol%, equivalent to 320 mg alcohol (ethanol) per tablespoon of syrup (15 ml) or 15 ml measuring cup, or 213 mg per 10 ml measuring cup.

Use of this medicinal product is dangerous for patients with alcoholism and must be taken into account in pregnant or breast-feeding women, children and high-risk groups, such as those with hepatic impairment or epilepsy. Ask your doctor for advice before taking this medicine.

Due to the presence of cochineal red A, this medicine may cause allergic reactions or asthma, especially in people allergic to aspirin.

Do not use this medicine to treat a productive cough. In such cases, coughing is a natural means of defence which is necessary for the removal of bronchial secretions.

If symptoms persist or if the cough becomes productive or is accompanied by bronchial congestion, expectoration (coughing up of bronchial secretions) or fever, please ask your doctor for advice.

In the event of chronic (long-term) disease of the bronchi and lungs accompanied by expectoration, medical advice is essential.

Codeine is converted to morphine by an enzyme in the liver. Morphine is the substance that produces the effects of codeine. Some people have variations of this enzyme, which can have a different impact from person to person. In some

people, the body converts codeine to morphine to a very low extent or not at all. In such cases, the codeine administered will not have any effect on the cough. Other people are more likely to experience serious adverse effects, because a very large amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and consult a doctor immediately: slow or shallow breathing, mental confusion, drowsiness, constricted pupils, nausea or vomiting, constipation, loss of appetite.

#### Precautions for use

In the case of liver failure (severe liver disease) or chronic liver disease, PLEASE ASK THE OPINION OF YOUR DOCTOR (see section 3 below).

The consumption of alcoholic beverages is not recommended during this treatment.

Do not take this medicine at the same time as a medicine to thin bronchial secretions (expectorant, mucolytic).

For diabetic patients: please note the sugar content (sucrose): 10.28 g per tablespoon.

IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU SHOULD ALWAYS TELL YOUR DOCTOR OR PHARMACIST ABOUT ALL OTHER TREATMENTS THAT YOU ARE TAKING

This medicine contains a cough suppressant called codeine. Other medicines may contain codeine or another cough suppressant. Do not combine these products, as you may exceed the recommended maximum dose (see Posology and method of administration).

#### Pregnancy and breast-feeding

##### Pregnancy

It is possible to take this medicine during your pregnancy, provided that it is for a short time (a few days) and at the recommended doses.

However, in the final stages of pregnancy, misuse of this medicine can cause harmful effects in the newborn. Therefore, always ask your doctor for advice before taking this medicine, and never exceed the recommended dose.

Ask your doctor or pharmacist for advice before taking any medicine.

##### Breast-feeding

Do not take EUPHON syrup while you are breast-feeding. Codeine and morphine pass into breast milk.

If codeine is taken by breast-feeding women at doses that are too high, this may cause respiratory pauses or reduced muscle tone in the infant. Ask your doctor or pharmacist for advice before taking any medicine.

##### Athletes

Warning: this medicine contains a substance that can trigger a positive result in anti-doping tests.

##### Driving and using machines

Drivers of vehicles (cars, motorcycles, bicycles, scooters) and operators of machines must be aware in particular of the possibility of drowsiness associated with the use of this medicine.

This effect fades after several doses; it may be preferable to start this treatment in the evening.

This effect is increased by the consumption of alcoholic beverages.

**List of excipients known to have a recognised action or effect:** alcohol, sucrose, cochineal red A [E124], methyl para-hydroxybenzoate [E218] and propyl para-hydroxybenzoate [E216].

### 3. HOW TO TAKE EUPHON SYRUP

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### **Dosage**

USE RESTRICTED TO ADULTS AND CHILDREN OVER THE AGE OF 12 (and weighing more than 40 kg).

For oral use

If you do not observe any effect, do not increase the dose beyond what is recommended, and do not take in combination with another cough suppressant, but consult your doctor.

The recommended dosage is:

• Adults and adolescents over the age of 15 years (and weighing more than 50 kg):

1 or 2 tablespoons (15 ml) or 1 or 2 measuring cups of 15 ml per dose, to be repeated after 6 hours if necessary, without exceeding 4 doses per day.

In elderly patients, doses are to be reduced by half. Ask your doctor for advice..

• Children aged 12 to 15 years (and weighing approximately 40-50 kg body weight):

Use the measuring cup provided in the packet: 1 measured dose (measuring cup) of 10 ml, to be repeated after 6 hours if necessary, without exceeding 4 doses per day.

#### **Special case**

In cases of liver failure (severe liver disease): the doses of codeine are to be reduced by half at the start of treatment.

Check with your doctor before taking this medicine.

#### **Frequency of administration**

The interval between doses should be a minimum of 6 hours.

This medicine should only be taken at the times when the cough occurs. For example, if the cough only occurs in the evening, a single dose may be sufficient.

#### **Duration of treatment**

Treatment should be of short duration (a few days) and limited to the times when coughing occurs.

**If you take more EUPHON syrup than you should:**

Ask your doctor for advice.

**If you forget to take EUPHON syrup:**

Resume treatment according to the prescription.

**Effects that may occur when treatment with EUPHON syrup is stopped:**

None, apart from the reappearance of the symptoms that motivated its prescription.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- constipation,
- drowsiness,
- dizziness,
- nausea, vomiting,
- difficulty breathing,
- allergic skin reactions

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (ANSM) [National Drug and Health Products Safety Agency] and network of Regional Pharmacovigilance Centres - Website: [www.ansm.sante.fr](http://www.ansm.sante.fr)

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE EUPHON SYRUP

Keep out of the sight and reach of children.

Do not use EUPHON syrup after the expiry date which is stated on the carton.

The bottle must be used within 30 days after opening.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. OTHER INFORMATION

What EUPHON syrup contains

#### **The active substances are:**

Codeine ..... 0,100 g

Dry aqueous extract of Erysimum officinale in maltodextrin (quantity of maltodextrin included in this amount of extract:

0.090 to 0.120 g) ..... 0,300 g

Per 100 ml syrup.

• **The other ingredients are:** citric acid monohydrate, cochineal red A (E124), natural raspberry flavour (alcoholate, alcoholature and concentrated raspberry extracts), methyl para-hydroxybenzoate (E218), propyl para-hydroxybenzoate (E216), alcohol, sucrose solution, purified water.

**Alcohol content:** 2.7 vol%.

1 tablespoon or measuring cup of 15 ml contains:

- 15 mg codeine
- 10.28 g sucrose
- 320 mg absolute alcohol

1 measuring cup of 10 ml contains:

- 10 mg codeine
- 6.85 g sucrose
- 213 mg absolute alcohol

1 measuring cup of 5 ml contains:

- 5 mg codeine
- 3.43 g sucrose
- 107 mg absolute alcohol

**What EUPHON syrup looks like and contents of the outer packaging**

This medicine is marketed in the form of a syrup.

Bottle of 150 ml or 300 ml with measuring cup.

#### **Marketing Authorisation Holder and Manufacturer**

##### **Marketing authorisation holder**

**LABORATOIRES MAYOLY SPINDLER**

6 AVENUE DE L'EUROPE

78400 CHATOU

##### **Distributor**

**LABORATOIRES MAYOLY SPINDLER**

6 AVENUE DE L'EUROPE

78400 CHATOU

##### **Manufacturer**

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**This leaflet was last approved in February 2016.**

Detailed information on this medicine is available on the ANSM (France) website.