



# STOPALGIC® CODEINE 600 mg/50 mg

# STOPALGIC® CODEINE 300 mg/25 mg

## Tablet

## Paracetamol / codeine

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. What STOPALGIC CODEINE is and what it is used for?
2. Before you use STOPALGIC CODEINE
3. How to use STOPALGIC CODEINE?
4. Possible side effects
5. How to store STOPALGIC CODEINE?
6. Further information

### 1. WHAT STOPALGIC CODEINE IS AND WHAT IT IS USED FOR

#### Pharmacological Class: Analgesic and antipyretic

STOPALGIC CODEINE is used in adults and children over 12 years. This medicine contains paracetamol and codeine: it is an analgesic (painkiller).

This product is indicated in treatment of moderate to severe pain that does not respond to the use of peripheral analgesics used alone.

### 2. BEFORE YOU USE STOPALGIC CODEINE

#### Do not take STOPALGIC CODEINE if:

- you are a child under 12 years old.
- you are aged under 18 years and you undergo tonsillectomy and/or adenoidectomy for obstructive sleep apnoea syndrome due to an increased risk of developing serious and life threatening adverse reactions
- you are allergic (hypersensitive) to paracetamol, codeine, or to any of the other ingredients

(these are listed in section 6, Further Information)

- you are taking any other paracetamol-containing products
- You have asthma or any conditions that affect your breathing
- You have liver disease

Before you take STOPALGIC CODEINE you should tell your doctor or pharmacist if you have:

- kidneys or liver diseases
- respiratory diseases (including asthma),
- bronchial congestion (cough with expectoration),
- gallbladder removal surgery.

### Special warnings

In case of overdose or mistakenly taking a dose too high, consult your doctor immediately.

This medicine contains paracetamol and codeine. Other medicines contain it. Do not combine them, so as not to exceed the recommended daily dose (see How to use STOPALGIC CODEINE).

- Prolonged use of this medicine may be addictive. Do not use for prolonged periods without medical advice.

- Do not exceed the dosages indicated and consult your doctor quickly in case of accidental overdose.

- Do not use for prolonged periods without doctor's advice, especially if the symptoms persist after 5 days and / or if any other signs occur after taking the medicine.

### Taking other medicines

This medication should be avoided with morphine agonists-antagonists (buprenorphine, nalbuphine, pentazocine) and with alcohol consumption.

If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, tell your doctor or pharmacist.

Report that you are taking this medicine if your doctor prescribes a dosage of uric acid or blood sugar.

### Taking STOPALGIC CODEINE with food and drink

Do not drink alcohol while taking STOPALGIC CODEINE. If you regularly drink large amounts of alcohol, you are at risk of damaging your liver when taking paracetamol.

### Interactions with herbal products or alternative therapies

Not applicable.

### Pregnancy

It is possible to take this medicine during pregnancy, for a short time (a few days) and at the recommended doses. However, in late pregnancy, over-taking of codeine can lead to toxicity in the newborn. Therefore, always seek the advice of your doctor before taking this medicine and never exceed the recommended dose.

### Breast-feeding

Do not take this medicine if you are breastfeeding because it contains codeine. Codeine and morphine pass into breast milk.

### Driving and using machines

Attention is drawn to the risks of drowsiness due to the presence of codeine in this drug, particularly among vehicle drivers and machine users. This phenomenon diminishes after several catches; it may be useful to start treatment at night. This phenomenon is accentuated by the consumption of alcoholic beverages.

### List of excipients with known effect

Not applicable.

### 3. HOW TO USE STOPALGIC CODEINE

Always take this medication exactly as prescribed in this leaflet or as directed by your doctor or pharmacist. Check with your doctor or pharmacist if in doubt.

### Dosage

Reserved for adults and teenagers from the age of 12 years.

The dosage depends on the intensity of the pain; the lowest effective dose should generally be used for the shortest possible duration.

The duration of treatment with this medication should not exceed 3 days. If pain is not relieved after 3 days, seek the advice of your

doctor.

Regular intakes prevent the pain from returning.

To avoid a risk of overdose, check the absence of codeine and paracetamol in the composition of other medicines, including medicines obtained without a prescription.

### -STOPALGIC CODEINE 600 mg/50 mg

1 tablet, to be renewed if necessary after 6 hours. Possibly, take 2 tablets in one dose in case of severe pain, without exceeding 6 tablets per day.

### -STOPALGIC CODEINE 300 mg/25 mg

1 tablet, to be renewed if necessary after 6 hours. Possibly, take 2 tablets in one dose in case of severe pain, without exceeding 12 tablets per day.

**NEVER TAKE MORE THAN 4 GRAMS OF PARACETAMOL PER DAY** (taking into account all medicines containing paracetamol in their formula). Always respect an interval of 4 hours minimum between the catches.

### Method and route of administration

Oral use.

The tablets are swallowed as is with a glass of water.

### Frequency of administration

In general, intakes are spaced 6 hours apart and at least 4 hours apart. In case of persistent pain, systematic catches prevent pain peaks.

In case of severe kidney disease (severe renal failure), the catch will be spaced at least 8 hours apart.

### Duration of treatment

If the pain persists more than 4 to 5 days, do not continue the treatment without the advice of your doctor.

**IN ALL CASES, COMPLY STRICTLY WITH THE MEDICAL PRESCRIPTION.**

### Symptoms and instructions in case of overdose

**If you take more STOPALGIC CODEINE tablet than you should:**

In case of overdose or accidental poisoning, urgently call a doctor. The main signs of codeine overdose are drowsiness and breathing difficulties.

### Instructions for omitting one or more doses

**If you forget to take STOPALGIC CODEINE, tablet:**

Continue the treatment according to the medical prescription.

Do not increase the dose and respect the time between shots.

### Risk of withdrawal syndrome

**If you stop taking STOPALGIC CODEINE, tablet:**

In case of prolonged treatment abrupt discontinuation of this drug may lead to withdrawal syndrome.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, STOPALGIC CODEINE can cause side effects, although not everybody gets them.

### RELATED TO THE PRESENCE OF CODEINE

Possibility of:

- feeling of falling asleep, euphoria, mood disorder,
- narrowing of the pupil, difficulty in urinating,
- hypersensitivity reaction (itching, hives, extensive rash),
- constipation, nausea, vomiting,
- drowsiness, dizziness,
- respiratory problems,
- abdominal pain especially in cholecystectomized patients (without gallbladder).

### RELATED TO THE PRESENCE OF PARACETAMOL

- In rare cases, it is possible that a rash or redness of the skin or an allergic reaction may occur, such as sudden swelling of the face and neck or sudden discomfort with a drop in blood pressure. Stop taking the medication immediately, tell your doctor, and never take any medicine containing paracetamol again.

- Exceptionally, biological changes requiring a check of the blood balance have been observed: abnormally low levels of certain white blood cells or certain blood cells such as platelets can result in bleeding nose or gums. In this case, consult a doctor.

### 5. HOW TO STORE STOPALGIC CODEINE

Keep out of the reach and sight of children.

### Expiry date:

The expiry date refers to the last day of that month.

Do not use STOPALGIC CODEINE after the expiry date which is stated on the carton after 'EXP'.

### Storage conditions:

This medicinal product does not require any special storage conditions.

**If necessary, a warning concerning certain visible signs of deterioration:**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. FURTHER INFORMATION

**What STOPALGIC CODEINE contains**

	STOPALGIC CODEINE 300mg/25mg	STOPALGIC CODEINE 600mg/50mg
<b>Active substance:</b>		
Paracetamol	300 mg	600 mg
Codeine phosphate hemihydrate	25 mg	50 mg
<b>The other components:</b>		
	croscarmellose sodium, crospovidone, stearic acid, talc	

**What STOPALGIC CODEINE looks like and contents of the pack**

**STOPALGIC CODEINE 600 mg / 50 mg** is in the form of tablets, box of 12 tablets. M.A. N°: 923 394 2

**STOPALGIC CODEINE 300 mg / 25 mg** is in the form of tablets, box of 16 tablets. M.A. N°: 923 394 1

### Delivery conditions:

List I

### Marketing authorization holder and manufacturer:

Les laboratoires MédiS

Tunis Road - KM 7 - PB 206 - 8000 Nabeul-Tunisia.

Tel : +216 72 235 006 / Fax : +216 72 235 016

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**This leaflet was last approved in March 2018.**

### This is a Medicament

- Medicament is a product but not like the others.

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children

