

**PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed
with a doctor's prescription only

CODICAL Tablets

Active ingredient: Codeine Phosphate 20 mg
Active ingredients: see section 6 – Further
Information. **Read this leaflet carefully in its entirety
before using the medicine.** This leaflet contains
concise information about the medicine.

**If you have further questions, refer to the doctor or
pharmacist.** This medicine has been prescribed for
you. Do not pass it on to others. It may harm
them even if it seems to you that their ailment is
similar. **The medicine is not intended for children
below 12 years of age.**

Clarification regarding pain treatment: Medicines
containing codeine will only be used to treat acute
pain (of short duration), of mild to moderate
intensity, only in patients over the age of 12 years
and only if the pain can not be treated with pain
killers such as paracetamol or ibuprofen. This is in
light of the fact that use of codeine may increase
the risk of respiratory depression.

1. WHAT IS THE MEDICINE INTENDED FOR?
The medicine is intended for the relief of mild to
moderate pain and for the symptomatic relief of
unproductive cough

Therapeutic group: analgesic, cough suppressant
from the opiate group

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- You are sensitive (allergic) to codeine or to any
other opiates or to any of the other ingredients
contained in the medicine.
- You are suffering, or have suffered in the past,
from impaired function of: the respiratory
system (e.g., asthma, during an asthma attack,
bronchitis, chronic pulmonary disease), heart
failure due to chronic pulmonary disease,
liver failure, head injury, intracranial pressure,
intestinal obstruction, alcoholism, diarrhea
resulting from poisoning or from antibiotics.
- You are taking antidepressants from the
monoamine oxidase inhibitors (MAOIs)
group, such as: selegiline, rasagiline, or are
within 14 days of discontinuing their use.
- **Do not give codeine to children and
adolescents above the age of 12 years and
under the age of 18 years** after a tonsillectomy
or adenoidectomy for treatment of obstructive
sleep apnoea, since these patients are more likely
than others to suffer from breathing problems.
- You are breastfeeding.
- **In children below 12 years of age,**
 - The preparation is not intended for people
known to produce a significant amount of
morphine from a dose of codeine (that belong
to the ultra-rapid metabolizers group), as they
are at increased risk of suffering from severe
side effects when using codeine.

**Do not use the medicine without consulting a
doctor before commencing treatment:**
If you are pregnant.

If you suffer, or have suffered in the past, from
impaired function of the: heart and/or blood vessels,
liver, kidney/urinary system, digestive system (e.g.,
ulcer, colitis, intestinal inflammation, severe bloody
diarrhea), thyroid, prostate (e.g., if you are suffering
from an enlarged prostate and from difficulty passing
urine), Addison's disease, gall bladder disease or
gallstones, convulsions, epilepsy, weakness, muscle
weakness (myasthenia gravis), low blood pressure
or a state of shock, addiction to drugs or medicines,
mental illness.

**Special warnings regarding use of the
medicine:**

The medicine is not recommended for treatment of
cough in children and adolescents between the ages
of 12-18 years, who are suffering from breathing
problems.

Medicines containing codeine will only be used to
treat acute pain (of short duration), of mild to
moderate intensity, only in patients over the age of
12 years and only if the pain can not be treated with
pain killers such as paracetamol or ibuprofen. This is
in light of the fact that use of codeine may increase
the risk of respiratory depression.

Naturally and rarely, in the bodies of some people
codeine is metabolized faster than in the majority
of the population. In these rare cases, high levels of
metabolites may accumulate and cause severe side
effects, such as: excessive sleepiness, confusion or
shallow breathing. In such cases, the patient should
be referred immediately for medical treatment.

In most cases it is impossible to know in advance
whether the patient belongs to the group of people
at risk for this effect.

Prolonged use may cause dependence!

Do not use this medicine frequently or for a prolonged
period without consulting the doctor. If you are
sensitive to any type of food or medicine, inform the
doctor before taking the medicine. Elderly patients
will be more sensitive to the effects of the medicine.
If you have to undergo any kind of surgery (including
dental surgery) or urgent treatment, inform the doctor
that you are taking this medicine.
Frequent and/or prolonged use of a preparation for
headache may exacerbate the pain.

**If you are taking, or have recently taken, other
medicines, including non-prescription medicines
and nutritional supplements, inform the doctor
or pharmacist. Especially, inform the doctor or
pharmacist if you are taking:**

Medicines that affect the central nervous system:
sedatives, hypnotics, medicines for epilepsy,
Parkinson's disease - such as: benzodiazepines,
barbiturates, antidepressants - monoamine oxidase
inhibitors - MAOIs (codeine can be taken 14 days
after discontinuing treatment with medicines from this
group); tricyclic antidepressants; alcohol; antiallergics
(antihistamines); opiate antagonists (e.g., naloxone,
naltrexone, buprenorphine); surgical anesthetics,
narcotic analgesics; anticholinergics (e.g., atropine);
antidiarrheals (loperamide, kaolin); anti-nausea
medicines (domperidone, metoclopramide);
antihypertensives; ciprofloxacin (antibiotic); medicines
to regulate heart rhythm (quinidine); cimetidine (to
treat stomach ulcer); antivirals (e.g., ritonavir).

Use of the medicine and food: Do not chew!
Swallow the medicine with food or water.

Use of the medicine and alcohol consumption:

Do not drink wine or alcoholic beverages during the
course of treatment with this medicine.

Pregnancy and breastfeeding: Do not use during
pregnancy unless instructed to do so by the doctor.
Do not use the medicine if you are breastfeeding,
since codeine passes into breast milk and may harm
the baby.

Driving and operating machinery: Do not
drive or operate machinery during the course of
treatment with the medicine until you know how the
medicine affects you, since this medicine may cause
drowsiness, confusion, dizziness, blurred or double
vision, hallucinations.

Use of the medicine and smoking: If you smoke –
tell the doctor before commencing treatment with
this medicine.

**Important information regarding some of the
ingredients of Codical:** Each tablet contains 80
mg lactose and less than 1 mg sodium. Do not
use if you have a sensitivity to lactose.

HOW SHOULD YOU USE THE MEDICINE?
Always use according to the doctor's instructions. If
you are uncertain about how to use the medicine,
consult the doctor or pharmacist.

**The usual dosage, unless otherwise prescribed
by the doctor:**

**For adults, adolescents and children above 12
years of age:** 1-2 tablets every 4 hours, and no
more than 6 tablets in 24 hours.

Do not exceed the recommended dose.

**This medicine is not intended for children below
12 years of age. Do not take medicines in the
dark! Check the label and the dose each time
you take a medicine. Wear glasses if you need
them. If there is no improvement in your condition
within 3 days, refer to the doctor. If you forget
to take this medicine at the required time, take a
dose as soon as you remember, but never take two
doses together.**

**Adhere to the treatment regimen as recommended
by the doctor.** Do not chew! Swallow the medicine
with food or water. Do not take the medicine with
alcoholic beverages. The tablet can be crushed.

**If you forget to take the medicine – do not take
a double dose.**

**If you accidentally took an overdose, or if a
child has accidentally swallowed the medicine,**
immediately refer to the doctor or proceed to a
hospital emergency room and bring the package
of the medicine with you. Do not induce vomiting
without explicit instruction from the doctor.

Possible signs of overdose: drowsiness,
weakness, tiredness, dizziness, vomiting, nausea,
sweating, confusion, drop in blood pressure, pupil
constriction, decreased respiratory rate, palpitations.
**Discontinuing use of the medicine after extended
use** may cause withdrawal symptoms, e.g., tremor,
sweating, increased heart and respiratory rate,
increased blood pressure, insomnia, restlessness,
agitation, anxiety, depression, anorexia, diarrhea, too
many tears, runny nose, sneezing, yawning, fever,
weakness, muscle contractions, dehydration.

**If you have further questions regarding use of the
medicine, consult the doctor or pharmacist.**

4. SIDE EFFECTS

As with any medicine, use of codeine may cause
side effects in some users. Do not be alarmed when
reading the list of side effects. You may not suffer

from any of them: dryness of the mouth, constipation,
nausea, vomiting, drowsiness, digestive system
disturbances.

**Discontinue treatment and refer to the doctor in
the following cases:**

Severe allergic reaction (rare): skin rash with irritation,
hives, difficulty breathing, increased sweating,
flushing, swelling, mainly of the face and throat,
fainting.

Eyes: blurred or double vision, pupil constriction
("pinpoint pupils").

Urinary system: pain/difficulty passing urine, urine
retention.

Nervous system: excessive drowsiness, weakness,
tiredness, dizziness, vertigo, fits, convulsions,
increased intracranial pressure (sore eyes, changes
in vision or headache in the area between the eyes),
headache, drug tolerance (the medicine has less
effect).

Psychiatric: mood swings, depression, hallucinations,
agitation, restlessness, nightmares, confusion,
excitation.

Heart: changes in heart rhythm, strong or irregular
heartbeat, drop in blood pressure, drop in blood
pressure in the transition from lying to standing.

Other: muscle stiffness, decreased libido, difficulty
breathing, low body temperature.

In the event that you experience side effects not
mentioned in this leaflet, or if there is a change in your
general health, consult with the doctor immediately.

**Side effects and drug interactions in children
and adolescents above 12 years of age:**

Parents must report to the attending doctor about
any side effect, as well as any additional medicine
being given to the child! See above for details of
special drug interactions and side effects.

Side effects can be reported to the Ministry of
Health by clicking on the link "Report Side Effects
of Drug Treatment" found on the Ministry of Health
homepage (www.health.gov.il) that directs you to
the online form for reporting side effects, or by
entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdverseEffectMedicamoh.qo.vil>

5. HOW SHOULD THE MEDICINE BE STORED?
Avoid poisoning! This medicine and any other
medicine must be kept in a safe place out of the reach
of children and/or infants to avoid poisoning. Do not
use the medicine after the expiry date (exp. date) that
appears on the package. The expiry date refers to the
last day of that month. Store below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine
also contains: Microcrystalline Cellulose, Lactose,
Talc, Magnesium Stearate, Colloidal Silicon Dioxide,
Sodium Starch Glycolate, Starch, FD&C Yellow No.6,
Aluminum Lake, FD&C Blue No.2 Aluminum Lake

**What the medicine looks like and the contents
of the package:** light brown tablets in a blister
package

License holder and manufacturer: Sam-On Ltd., 25
Haavoda St., Bat-Yam
This leaflet was checked and approved by the
Ministry of Health in 7/2016

Registration number of the medicine in the National
Drug Registry of the Ministry of Health: 443723143