DI-ANTALVIC®
+ Codeine
new combination

Paracetamol + Codeine
Scored Tablets

sanofi aventis

Please read all of the leaflet carefully before taking this medicine.
- Keep this leaflet you may need to read it again.
- If you have any other questions or doubts, ask your doctor or pharmacist for further information.
- This medicine has been prescribed personally for you. Do not give it to anybody else, even if he/she has identical symptoms since it might cause harm to him/her.

IDENTIFICATION OF THE MEDICINE

Composition

Paracetamol.....400.00 mg
Codeine phosphate hemihydrate.....20.00 mg
Quantity equivalent to codeine base.....15.62 mg

Excipients: gelatin, stearic acid, potato starch, povidone, crospovidone.
For one scored tablet.

Pharmaceutical form and presentation

Scored tablets, box of 16 or 20.
Not all pack sizes may be marketed.

Pharmaco-therapeutic class

PERIPHERAL ANTALGIC.
OPIOID ANALGESIC
(N: central nervous system)

Packed by Benta SAL Dbayeh – Lebanon
under license from Sanofi Aventis France

WHEN THIS MEDICINE SHOULD BE USED

For adults only (from 15 years of age).
This medicine contains paracetamol and codeine.
Treatment of moderate to intense pain that is not relieved by aspirin, paracetamol or ibuprofen used alone.

ATTENTION!
WHEN THIS MEDICINE SHOULD NOT BE USED

NEVER TAKE this medicine:
− If you are allergic to any of the ingredients,
− If you have serious liver disease,
− If you are asthmatic,
− If you have respiratory difficulties,
− If you are breast-feeding, when treatment is long-term.

IF YOU HAVE ANY DOUBTS, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Special warnings

In the event of overdose, or accidental intake of an excessive dose, consult your doctor immediately.
Taking this medicine for long periods may lead to addiction.
This medicine should not be used for long periods without medical advice.

This medicine contains paracetamol and codeine, as do some other medicines. Do not take this medicine with other medications containing these substances, so as not to exceed the maximum recommended doses (see "Dosage and Method of administration").

Special precautions for use

Alcohol should not be consumed during treatment.

Inform your doctor if you:
− have kidney or liver disease,
− have respiratory disease (including asthma),
− have bronchial congestion (productive cough),
− have had gallbladder surgery.

IF YOU HAVE ANY DOUBTS, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE

Drug interactions and other interactions

This medicine should not be combined with morphine agonists/antagonists (buprenorphine, nalbuphine, pentazocine), naltrexone or alcohol.

TO AVOID ANY INTERACTION BETWEEN DIFFERENT MEDICINES, YOU MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU MAY BE TAKING.

Inform your doctor that you are taking this medicine, if he/she prescribes tests to determine blood uric acid level.

Pregnancy-Lactation

Pregnancy
This medicine can be taken during pregnancy for a short period (a few days) and at the recommended doses.
However, at the end of pregnancy, excessive intake of codeine may cause toxicity in the newborn infant. Consequently, you should 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
This medicine is excreted in breast milk.
Excessive doses of codeine administered to breast-feeding women may cause pauses in breathing or reduced muscle tone in infants. Apart from occasional use, this medicine is contraindicated while breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

Drivers and machine operators

The attention of patients, particularly those who drive or use machines, should be drawn to the risk of drowsiness due to the codeine content of this medicine. This effect subsides after several doses; it may be beneficial to start treatment in the evening. This effect is exacerbated by the consumption of alcoholic beverages.

HOW TO USE MEDICINE

Dosage

FOR ADULTS AND CHILDREN FROM 15 YEARS OF AGE ONLY.

One tablet, repeated after 4 to 6 hours if necessary, or possibly 2 tablets as a single dose for intense pain, without exceeding 6 tablets per day.

NEVER TAKE MORE THAN 4 g OF PARACETAMOL PER DAY
(taking into account all medicines containing paracetamol).

THIS MEDICINE HAS BEEN GIVEN TO YOU PERSONALLY, IN A SPECIFIC SITUATION.
- IT MAY NOT BE SUITABLE FOR USE IN ANOTHER SITUATION,
- DO NOT PASS IT ON TO OTHERS.

IF YOU HAVE ANY DOUBTS, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Method and route of administration
Oral use.
The tablets are to be swallowed with a glass of water.

Frequency and time of administration
The doses are generally taken every 6 hours, and at least 4 hours apart. When pain persists, following a regular dose schedule makes it possible to avoid peaks in the intensity of pain. In patients with serious kidney disease (severe renal insufficiency), doses must be taken at least 8 hours apart.

Treatment duration
If pain persists for more than 4 to 5 days, do not continue treatment without asking your doctor's advice.

Management of overdose
In the event of overdose, or accidental intake of an excessive dose, consult your doctor urgently.
The main signs of codeine overdose are drowsiness and breathing difficulties.

Management in the event of omission of one or several doses
Do not increase the dose and respect the intervals between dosing.

Risk of withdrawal syndrome
There is a risk of withdrawal syndrome if treatment is suddenly discontinued following prolonged use.

UNWANTED AND UNPLEASANT EFFECTS

LIKE ANY ACTIVE PRODUCT THIS MEDICINE MAY, IN CERTAIN PERSONS, GIVE RISE TO VARYING DEGREES OF UNPLEASANT EFFECTS:

Codeine - related effects
Codeine can cause the following:
− feeling of sleepiness, euphoria, mood changes,
− contraction of the pupil, difficulty in urinating,
− allergic reactions (itching, urticaria, widespread skin rash),
− constipation, nausea, vomiting,
− drowsiness, dizziness,
− difficulty breathing,
− abdominal pain, particularly in patients who have had a cholecystectomy (gallbladder removal),
− very rare cases of damage to the pancreas.

Paracetamol-related effects
- In certain rare cases, skin rash or redness, or an allergic reaction may occur, showing as sudden swelling of the face and neck, or sudden malaise with a fall in blood pressure. You must stop treatment immediately and inform your doctor, and never take any medicines containing paracetamol again.
- Exceptional cases of abnormal laboratory values have been observed, requiring blood count tests: abnormally low levels of certain white blood cells or blood cells such as platelets, possibly causing nosebleeds or bleeding gums. If this occurs, seek medical advice.

DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE AND IF YOU NOTICE ANY UNWANTED AND UNPLEASANT EFFECTS NOT MENTIONED IN THIS LEAFLET, OR IF CERTAIN UNWANTED AND UNPLEASANT EFFECTS BECOME SERIOUS, PLEASE INFORM YOUR DOCTOR OR PHARMACIST

STORAGE

Keep out of the reach and sight of children.
DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING.

Special precautions for storage
Do not store above 30°C.

DATE OF LEAFLET REVISION
April 2009

This is a medicament
- A 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
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists