DI-ANTALVIC FOR ADULTS

QUALITATIVE AND QUANTITATIVE COMPOSITION

Dextropropoxyphene hydrochloride 30 mg
Paracetamol ..... 400 mg
Excipients : magnesium stéarate
per capsule

capsule shell : gelatin, titanium oxide, indigotin, yellow iron oxide, sulfuric anhydride.

PRESENTATION FORM

Box containing 20 capsules under thermoformed alveolar patches.

PHARMACOTHERAPEUTIC CATEGORY

Peripheral analgesic/opioid
(N : central nervous system)

PERSON RESPONSIBLE FOR PLACING THE PRODUCT ON THE MARKET

NAME AND ADDRESS

Laboratoires HOUDE
1, terrasse Bellini
92910 Paris La Défense Cedex
Tel. 01 40 81 42 00

MANUFACTURER'S NAME AND ADDRESS

USIPHAR
F. 60200 Compiègne

CASE(S) IN WHICH THIS DRUG CAN BE USED

(THERAPEUTIC INDICATIONS)

This medicine is a combination of two active ingredients : it is an analgesic (which relieves pain)
This medicine is recommended for the treatment of moderate or severe pain which is not relieved by aspirin or paracetamol alone.

CAUTION !

CASE(S) IN WHICH THIS DRUG MUST NOT BE USED

This medicine should not be used in the following cases
- children under the age of 15 years,
- know allergy to paracetamol and/or dextropropoxyphene,
- severe kidney or liver desease,
- breast feeding (see section on Pregnancy and Breast-feeding).

Unless your doctor decides to the contrary, this medicine should not generally be used in the event of treatment with carbamazepine (a compound used to treat epilepsy).
IF YOU HAVE ANY DOUBT, ASK YOUR PHYSICIAN OR PHARMACIST FOR ADVICE.

SPECIAL WARNING

Avoid the consumption of alcoholic beverages.
Prolonged use at high doses may give rise to a state of dependency.

PRECAUTIONS FOR USE

Do not exceed the recommended dose.
If you are receiving treatment with an antidepressant or a tranquillizer, consult your doctor before taking this medicine.
IF YOU HAVE ANY DOUBT, ASK YOUR PHYSICIAN OR PHARMACIST FOR ADVICE.

DRUG INTERACTIONS AND OTHER INTERACTIONS

IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL DRUGS, SYSTEMATICALLY INFORM YOUR PHYSICIAN OR PHARMACIST OF ANY OTHER CURRENT TREATMENT.

In particular, inform your doctor or pharmacist if you are receiving a treatment for epilepsy which contains carbamazepine.

This medicine contains paracetamol, other medicines also contain this compound. In order not to exceed the daily recommended dose (3 g), do not take other such medicines at the same time.

PREGNANCY AND BREAST-FEEDING

Your doctor may consider it necessary for you to receive this medicine during pregnancy. In all cases, you should comply with the dosage and duration of treatment which have been prescribed

for your case.
This medicine passes into breast milk.
When administered in a breast-feeding mother, it may cause respiratory pauses or lowered tone in the infant. Consequently, this medicine is contraindicated in breast-feeding mothers.

DRIVERS AND MACHINE OPERATORS

This medicine may cause dizziness and drowsiness.

SPORTMEN

Warning : take care, this speciality contains an active product which can induce in a positive way during antidoping controls.

HOW TO USE THIS MEDICATION

DOSAGE

Reserved for use in adults from the age of 15 years.

Follow your doctor's prescription.

Generally, 4 capsules per day at regular intervals. Capsules should be swallowed with a large glass of water, and taken for preference at the same time as a meal or snack.

Do not exceed 6 capsules per day.

MODE AND ROUTE OF ADMINISTRATION

Oral route.

FREQUENCY AND TIME OF ADMINISTRATION OF THE DRUG

Doses should be taken at intervals of six hours (or a minimum of 4 hours), capsules should be taken during at meal or snack.

In the event of renal failure, doses should be taken at 8 hours intervals.

TREATMENT DURATION

Do not use for prolonged periods.

IN ALL CASES, ALWAYS STRICTLY COMPLY WITH YOUR DOCTOR'S PRESCRIPTION

MANAGEMENT OF OVERDOSE

Take medical advice in the event of overdose or accidental poisoning.

RISK OF WITHDRAWAL SYNDROME

Risk of dependency in the event of prolonged use at high doses.

ADVERSE REACTIONS

Like all active products, this medicine may, in certain people, give rise to varying degrees of unpleasant effects.

The following may occur in certain rare cases : skin rash (red lesions on the skin) or allergic reaction : **stop the treatment immediately and inform a doctor.**

This medicine may, in certain people, give rise to varying degrees of unpleasant effects :

- nausea, vomiting.
- or abdominal pain, constipation, dizziness, minor visual disorders, headaches, fatigue, sleepiness, euphoria, disorientation,
- hypoglycemia (lowering of blood sugar levels, resulting in sweating, problems with concentration or mood, malaise),
- hepatitis (liver impairment, with possible yellow colouring of the eyes or skin).

INFORM YOUR PHYSICIAN OR PHARMACIST OF ANY ADVERSE REACTION THAT IS NOT MENTIONED IN THE LEAFLET.

CONSERVATION

DO NOT EXCEED THE EXPIRY DATE WHICH IS CLEARLY INDICATED ON THE PACKAGING.

PACKAGE INSERT REVISION DATE

Octobre 1996

LABORATOIRES
HOUDE

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