

ACUPAN®

NEFOPAM

1. NAME OF THE PRODUCT

ACUPAN® solution for injection

COMPOSITION

Nefopam (hydrochloride).....20 mg

Excipients: Disodium phosphate and sodium phosphate, water for injection q.s. 2 ml.

PHARMACEUTICAL FORM

Solution for injection in 2 ml glass ampoule. Box of 5 ampoules.

PHARMACO-THERAPEUTIC GROUP

OTHER ANALGESICS AND ANTIPYRETICS

NAME AND ADDRESS OF THE HOLDER

BIOCODEX, 7 avenue Gallieni, 94250 GENTILLY, France

NAME AND ADDRESS OF THE MANUFACTURER

BIOCODEX, 1 avenue Blaise Pascal, 60000 BEAUVAIS, France

2. WHEN TO USE THIS MEDICINE?

Symptomatic treatment of acute painful conditions, specially post-operative pains.

3. WARNING!

When not to use this medicine?

DO NOT USE this medicine in the following situations:

- Known hypersensitivity to nefopam or to one of the components of Acupan.
- Children below 15 years.
- Previous history of convulsions.
- Urinary retention linked to urethroprostatic disorders.
- Acute angle glaucoma (increase of pressure into the eye).

WHEN IN DOUBT, IT IS ADVISABLE TO ASK YOUR PHYSICIAN OR PHARMACIST FOR ADVICE.

Warnings

A risk of addiction exists with Acupan.

In case of concomitant use of a morphinic drug, the brutal stopping of the morphine drug can provoke a withdrawal syndrome because ACUPAN is not a morphinic agent.

Precautions for use

Use this medicine with precaution:

- In case of hepatic insufficiency;
- In case of renal insufficiency;
- In patients having a cardiovascular pathology because of the tachycardic effect of this drug (increase of cardiac frequency);
- Due to its anticholinergic effects, the treatment with Acupan is not advisable for elderly people.

WHEN IN DOUBT DO NOT HESITATE TO ASK YOUR PHYSICIAN OR YOUR PHARMACIST FOR ADVICE.

Drug interactions and other kind of interactions

ACUPAN can interact with other drugs.

IN ORDER TO AVOID POSSIBLE DRUG INTERACTIONS YOU MUST INFORM SYSTEMATICALLY YOUR PHYSICIAN OR YOUR PHARMACIST ABOUT ANY OTHER CURRENT TREATMENT.

Pregnancy and breast-feeding

The effect of this medicine during pregnancy or breast-feeding is unknown. Consequently, the use of this medicine is not advisable during pregnancy and breast-feeding.

ASK YOUR PHYSICIAN OR YOUR PHARMACIST BEFORE TAKING ANY MEDICINE.

Driving and using machines

Due to the possible risk of giddiness, the drivers and machine users have to be vigilant.

4. HOW TO USE THIS MEDICINE?

Dosage

The dosage is strictly individual.

It is generally 1 ampoule (IV or IM route) per intake, to be renewed until 6 ampoules per day if necessary.

Mode and way of use

ACUPAN can be administered by deep intramuscular route (IM) or slow intravenous infusion (IV) (more than 15 minutes). By IV route, it is necessary to lay down in order to avoid some side effects such as nausea, dizziness, sweats.

How to open the ampoules:

The ampoule is precut in a point of its neck. The coloured spot on the olive allows the orientation of this one. Take the ampoule, the coloured point directed towards yourself. The ampoule opens easily while placing the thumb on the coloured spot and by exerting a light inflection top downwards as indicated on the drawing.



Frequency and time to take it

The injections can be renewed every 6 hours (IM route) or every 4 hours (IV route).

Duration of treatment

The duration of the treatment prescribed by your physician must be strictly respected.

Overdosage

The accidental overdosage can lead to possible cardiovascular troubles, convulsions, hallucinations which need a monitoring of the cardiac and respiratory functions with in-hospital treatment of the symptoms.

CONSULT IMMEDIATELY YOUR PHYSICIAN OR YOUR PHARMACIST.

If you forget to take this medicine

When one injection has been forgotten, it is not necessary to increase the next intake.

Withdrawal syndrome

The stopping of the treatment does not provoke withdrawal syndrome (state of deprivation or lack felt after the stop of certain drugs with reappearance or worsening of the disorders).

5. POSSIBLE SIDE EFFECTS

AS FOR ALL ACTIVE PRODUCT, THIS DRUG CAN, IN SOME PATIENTS, LEAD TO MORE OR LESS IMPORTANT ADVERSE EFFECT.

The most current side effects are: vertigo, nausea with or without vomiting, somnolence, sweats, pain at the injection site.

It has also been observed troubles such as dryness of mouth, acceleration of heartbeat, palpitations, urinary retention.

More rarely have been reported: excitability, irritability, faintness, hallucination, abuse, drug addiction, convulsions, allergic reactions (urticaria, Quincke's oedema, anaphylactic shock)

INFORM YOUR PHYSICIAN OR YOUR PHARMACIST ABOUT EVERY SIDE EFFECT NOT MENTIONED IN THIS LEAFLET.

6. STORAGE

No special conditions for storage.

Do not use after the expiry date printed on the outer pack.

Keep out of reach and sight of children.

7. DATE OF REVISION OF THE TEXT

March 2007