

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

ACUPAN 20 mg / 2 ml Nefopam hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

- 1 What ACUPAN solution for injection is and what it is used for
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1 WHAT ACUPAN SOLUTION FOR INJECTION IS AND WHAT IT IS USED FOR

ACUPAN contains nefopam as active ingredient. It belongs to the group called "OTHER ANALGESIC AND ANTIPYRETICS" (N : Central nervous system) ATC code: N02BG06

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

2. WHAT YOU NEED TO KNOWN BEFORE YOU TAKE ACUPAN solution for injection

Contra-indications

DO NOT TAKE ACUPAN solution for injection:

In the following cases:

- If you are allergic to nefopam or any of the other ingredients of this medicine (listed in section 6).
- acute angle glaucoma (increase of pressure into the eye).
- urinary retention linked to urethroprostatic disorders.
- previous history of convulsions.
- children below 15 years.

Warnings and precautions

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:

- In case of hepatic insufficiency
- In case of renal insufficiency
- If you suffer from a cardiovascular pathology you should not take this medicine as it can increase the cardiac frequency.
- Due to its cholinergic effects, the treatment with Acupan is not advisable for elderly people.

Other medicines and ACUPAN solution for injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Acupan could interact with other medicines.

Pregnancy and breast-feeding

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

Driving and using machines

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

Noticeable excipients

None

3. HOW TO TAKE ACUPAN solution for injection?

Dosage

The dosage is strictly individual.

The recommended dose is generally 1 ampoule (IV or IM route), 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 route (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.

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.

If you take more ACUPAN solution for injection than you should

The accidental overdose 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 ACUPAN solution for injection

Do not take a double dose to make up for a forgotten dose.

If you stop taking ACUPAN solution for injection

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

If you have any further questions on the use of this product, ask your doctor or your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects are (may affect up to 1 in 10 people): 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 (may affect up to 1 in 10,000 people) have been reported: excitability, irritability, hallucinations, abuse, drug addiction, convulsions, allergic reactions (urticaria, Quincke's oedema, anaphylactic shock).

Other side effects of not known frequency (cannot be estimated from available data) have also been observed: coma, confusion.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE ACUPAN solution for injection?

Keep this medicine out of the sight and reach of children.

After opening/reconstitution/dilution: the product must be used immediately.

Do not use this medicine after the expiry date which is stated on the carton.

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

No special conditions for storage.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ACUPAN solution for injection contains?

The active substance is:

Nefopam hydrochloride..... 20 mg

For one 2 mL-ampoule.

The other ingredients are:

Disodium phosphate and sodium phosphate, water for injection q.s. 2 mL.

What ACUPAN solution for injection looks like and contents of the pack

2 mL-glass ampoule containing a clear, colourless solution for injection.

Box of 5 ampoules.

Marketing Authorization Holder and manufacturer

Marketing Authorization Holder

BIOCODEX

7 avenue Gallieni

94250 Gentilly

France

Manufacturer responsible for batch release

BIOCODEX

1 avenue Blaise Pascal

BEAUVAIS

France

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