



Naltrexone Hydrochloride  
50mg film-coated tablets.

## Patient Information Leaflet

### What you should know about Opizone® 50 mg film-coated tablets

The name of your medicine is Opizone® 50 mg film-coated tablets\*.

\* Abbreviated to Opizone in text.

Please read this leaflet carefully before you start taking your medicine. This leaflet provides a summary of the information available on your medicine. If you have any questions or are not sure about anything ask your doctor, pharmacist, or community drugs worker.

### What is in your medicine?

Each beige coloured tablet contains 50 mg naltrexone hydrochloride, as the active ingredient. The following ingredients are also contained in each tablet:

Silica colloidal anhydrous, magnesium stearate, cospovidone, powdered cellulose, microcrystalline cellulose, lactose monohydrate.

The film coating on the outside of the tablet contains lactose monohydrate, hypromellose, titanium dioxide (E 171), macrogol 4000, black iron oxide (E172), red iron oxide (E 172), yellow iron oxide (E 172).

Opizone is available in packs of 7, 14 and 28 tablets. Not all pack sizes might be marketed.

### Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder of this medicine is:

AOP Orphan Pharmaceuticals AG,  
Wilhelminenstrasse 91/IIIf/B4, 1160 Vienna, Austria

The manufacturer is:

Haupt Pharma, Wolfratshausen, Germany.

### What is your medicine used for?

The active ingredient, naltrexone hydrochloride, belongs to a group of medicines called opioid or opiate antagonists. It is used as part of a treatment programme to help you stop taking opiates and remain off them.

Opizone prevents the euphoric feelings you experience after taking opiates. In treatment for withdrawal from opiates it will reduce the craving you may experience. Opizone does not cause dependency.

### Before taking your medicine

- Do you think you might be allergic to naltrexone hydrochloride or any of the other ingredients of the tablets?
- Are you under 18 years of age?
- Do you have kidney problems?
- Do you have hepatitis or other liver problems?
- Are you pregnant or think you might be pregnant?
- Are you breast feeding?
- Are you currently using opiates or have you had a positive urine test for opiates within the last 7-10 days?
- Do you have acute withdrawal symptoms at the moment?
- Have you recently failed to come off opiates because of severe withdrawal symptoms?
- Are you suffering withdrawal symptoms because of a recent injection of naloxone?
- If you have been told by your doctor that you have intolerance to some sugars, you should tell your doctor before taking Opizone tablets.

If the answer to any of the above questions is YES, or you are unsure, you should tell your doctor or community drugs worker before taking Opizone tablets.

### Warnings

**Never** take opiates after taking Opizone tablets. Although Opizone will normally block their effects, there is a risk that if you were to take opiates these could be in your body after the effects of Opizone have passed. You could, therefore, unintentionally overdose, which could have severe consequences, or even be fatal.

After treatment with Opizone you will most likely be more sensitive to the effects of opiates. You could unintentionally overdose, even if you were to take your usual dose of opiates. You could overdose with very severe consequences. In extreme cases, this may be fatal.

You must tell every doctor who treats you that you are taking Opizone tablets.

You must not give Opizone to another person, even if they have the same symptoms as you.

If you become pregnant you must inform your doctor.

Please make sure that your Opizone tablets are stored out of the sight and reach of children.

## Driving and using machines

Opizone may make you feel less alert or drowsy. You should not drive or operate machinery if affected.

## Use with other medicines

Please inform your doctor about any other medicine you take, before starting Opizone. Some common medicines contain opiates and these will not work when you are taking Opizone. Therefore, inform your doctor or pharmacist if you need cough-mixtures or medicines for diarrhoea or pain. You can then be prescribed or recommended medicines that do not contain opiates.

## Taking your medicine

The initial dose of Opizone on the first day of treatment is half a tablet (25mg). Thereafter, the usual dose is one 50mg tablet each day. Your doctor may prescribe a different dosage depending on your individual requirements; you should discuss this with your doctor. You should always follow your doctor's instructions. If you are unsure about anything your pharmacist or drugs worker may be able to help.

Opizone is usually taken for at least three months. Your doctor will decide exactly how long you will need to take this medicine.

## What to do if you miss a dose

If you forget to take a dose, take another as soon as you remember. However, if it is almost time for your next dose, miss the forgotten dose altogether and continue with the tablets as before.

## What to do if you take too much medicine

Always take the tablets according to the instructions from your doctor or community drugs worker. If you take more tablets than instructed, tell your doctor or community drugs worker immediately, or contact your local hospital emergency department.

Do not drive whilst taking Opizone as they may make you feel sleepy.

## After taking your medicine

As with all medicines, Opizone may cause some unwanted side effects in some people.

The following unwanted effects have been reported in patients withdrawing from opiates, but have also been reported in patients taking naltrexone hydrochloride tablets.

## Very Common

Headaches, difficulty sleeping, feeling restless, nervousness, stomach pain or cramps, feeling or being sick, joint and muscle pains, feeling weak and lacking energy.

## Common

Increased energy, feeling despondent or irritable, mood swings, anxiety, feeling thirsty, dizziness or loss of balance, shivering, increased sweating, watery eyes, chest pains, diarrhoea or constipation, rash, difficulty in urinating, difficulty in ejaculation, impotence, loss of appetite.

## Rare

Feeling depressed, feeling suicidal, difficulty speaking, liver disorders.

## Very Rare

Decrease in the number of blood cells (platelets), which may make you bruise more easily, feeling agitated, hallucinations, euphoria, shakiness, skin rash.

You should tell your doctor, pharmacist or drugs worker if you experience any unwanted effects which you feel could be caused by Opizone.

## Storing your medicine

The expiry date of your tablets is shown on the carton and blister. Do not take Opizone after the expiry date.

Any out of date medicines should be returned to your pharmacist for disposal.

Do not store above 25°C.

Store in the original package.

REMEMBER keep all medicines out of the sight and reach of children.

This medicine is for you only. Never give it to others, even if they have the same symptoms as you, as it may harm them.

This leaflet applies to Opizone only. Do not throw it away until you have finished your medicine, you may want to read it again.

## Date of leaflet preparation:

February 2006