

Package leaflet: information for the patient

Adaptol 500 mg tablets

Mebicarum

Read all of this leaflet carefully before you start using 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 signs of illness 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. See section 4.

What is in this leaflet

1. What Adaptol is and what it is used for
2. What you need to know before you use Adaptol
3. How to use Adaptol
4. Possible side effects
5. How to store Adaptol
6. Contents of the pack and other information

1. What Adaptol is and what it is used for

Mebicar, the active substance of Adaptol, belongs to the group of medicines called anxiolytics. They eliminate or weaken unrest, anxiety, fear, inner emotional tension and irritability. These effects are not accompanied by muscle relaxation and movement coordination disorders, mental and physical activity suppression. Therefore, Adaptol can be administered not interrupting work or study.

The medicine has no direct hypnotic effect, but it increases activity of hypnotics and normalizes disturbed sleep. Mebicar relieves or takes off nicotine abstinence that occurs after smoking discontinuation. Mebicar does not cause elevated mood or euphoria. No drug tolerance or dependence, or withdrawal syndrome have been observed with its administration.

Therapeutic indications:

- neuroses and neurotic disorders (anxiety, emotional lability, unrest, fear);
- cardialgias (chest pain) of different origin, which are not connected with cardiovascular diseases;
- to improve tolerability of neuroleptics and tranquilizers (to reduce emotional depression, excessive sedative effect and muscle weakness caused by these medicines);
- in complex therapy to decrease an inclination for smoking.

2. What you need to know before you use Adaptol

Do not take Adaptol

- if you are allergic to mebicar or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Adaptol.

Children and adolescents

Adaptol is not recommended for use in children and adolescents up to 18 years of age.

Other medicines and Adaptol

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

Adaptol can be used concomitantly with neuroleptics, tranquilizers (benzodiazepines), hypnotics, antidepressants and psychostimulants.

Adaptol with food, drink and alcohol

You may take this medicine without regard to meals.

Do not use Adaptol with alcoholic beverages.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Adaptol is not recommended during pregnancy and breast-feeding period.

Driving and using machines

The medicine may cause hypotension and weakness that may affect the ability to drive and use machines.

3. How to use Adaptol

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The medicine can be used without regard to meals.

For adults, the recommended dose is 300-500 mg 2-3 times a day. The maximum single dose is 3 g, the maximum daily dose is 10 g. The course of treatment ranges from few days up to 2-3 months.

In complex therapy to decrease an inclination for smoking, the dose of 600-1000 mg a day for 5-6 weeks are used.

Adaptol 300 mg hard capsules and Adaptol 500 mg tablets are available on the market; the doctor will choose the suitable strength and dosage form for each patient individually.

For elderly, no dose adjustment is required.

For patients with liver failure, no dose reduction is required.

In patients with kidney failure, dose adjustment is not studied. These patients should use the medicine with caution.

If you feel that the effect of the medicine is too weak or too strong, consult your doctor.

Use in children and adolescents

Adaptol is not recommended for use in children and adolescents up to 18 years of age.

If you take more Adaptol than you should

If you have taken more Adaptol than you should, consult your doctor.

If you forget to take Adaptol

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

If you stop taking Adaptol

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

4. Possible side effects

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

Rare (affects less than 1 in 1,000 patients):

- dizziness;
- low blood pressure;
- indigestion;
- low body temperature, weakness;
- allergic reactions (skin itching) with high doses.

In case of allergic reaction, the medicine should be discontinued.

In cases when low blood pressure and/or decreased body temperature occur (body temperature may decrease for 1-1.5 °C), the medicine should not be discontinued. Blood pressure and body temperature normalize when the treatment is discontinued.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Adaptol

Do not store above 25 °C. Protect from light and moisture.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package after “Expiry date”. The expiry date refers to the last day of that month.

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 Adaptol contains

The active substance is mebicar (*Mebicarum*). Each tablet contains 500 mg of mebicar. The other ingredients are methylcellulose, calcium stearate.

What Adaptol looks like and contents of the pack

White or almost white, round, flat tablets with bevelled edge and break line on one side of the tablet.

The score line is only for breaking the tablet for ease of swallowing and not to divide into equal doses.

10 tablets in blister from transparent PVC film and aluminium foil.

2 blisters (20 tablets) together with the package leaflet in a cardboard box.

Marketing Authorisation Holder and Manufacturer

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