

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### ADAPTOL 500 mg Tablets ADAPTOL 300 mg Hard Capsules Mebicar

**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.

#### **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**

The active substance of *Adaptol* – mebicar belongs to the group of medicines called anxiolytics – they eliminate or reduce unrest, anxiety, fear, inner emotional tension and irritability. These effects are not accompanied by myorelaxation and movement coordination disorders, mental and physical activity suppression, therefore *Adaptol* can be administered not interrupting work or study.

The preparation has no direct hypnotic effect, but it increases activity of hypnotics and normalizes disturbed sleep process. Mebicar relieves or eliminates nicotine abstinence that occurs after smoking discontinuation. Mebicar does not cause elevated mood or euphoria, no medicine dependence or withdrawal syndrome has been observed during its administration.

#### ***Adaptol* is used according to the following indications:**

- Neuroses and neurotic disorders (anxiety, emotional lability, unrest, fear).
- Cardialgias of different origin, which are not associated with cardiovascular diseases.
- To improve tolerability of neuroleptics and tranquilizers (these preparations cause emotional depression, excessive sedative effect and muscle weakness).
- Complex therapy to decrease an inclination for smoking.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE ADAPTOL**

##### **Do not take *Adaptol***

- if you have allergy to mebicar or any of the other ingredients of the preparation (listed in section 6.).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking *Adaptol*.

##### **Children and adolescents**

*Adaptol* is not recommended for children under 18 years of age.

### **Other medicines and *Adaptol***

Please 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 independently of food intake.

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.

The use of this medicine during pregnancy and breast-feeding is not recommended.

### **Driving and using machines**

The medicine may cause hypotension and weakness that may have an effect on the ability to drive a motor vehicle and use machines.

## **3. HOW TO USE ADAPTOL**

Always use this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The medicine should be taken orally independently of food intake.

The recommended dose in *adults* is 300-500 mg 2-3 times a day.

The highest single dose is 3 g, the highest daily dose – 10 g. The course of treatment – from a few days up to 2-3 months.

Complex therapy to decrease an inclination for smoking – 600-1000 mg a day for 5-6 weeks.

*Elderly* should not adjust the dose.

No dose reduction is required in *patients with liver failure*.

Dose adjustment is not studied in *patients with kidney failure*. These patients should use the medicine with caution.

If you feel the effect of your 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 under 18 years of age.

### **If you take more *Adaptol* than you should**

If you have taken more *Adaptol* than you should, immediately 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 product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

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

Frequency of undesirable effects:

Very common – 1 or more than 1 in 10 patients;

Common – less than 1 in 10, but more than 1 in 100 patients;

Uncommon – less than 1 in 100, but more than 1 in 1000 patients;

Rare – less than 1 in 1000, but more than 1 in 10 000 patients;  
Very rare – less than 1 in 10 000 patients;

*Rare:* low blood pressure, dizziness, gastrointestinal disorders, low body temperature, weakness, allergic reactions (skin itch) are possible after administration of high doses. In case of allergic reactions, the use of the medicine should be discontinued.

In cases when low blood pressure and/or decreased body temperature occurs (body temperature may decrease by 1-1.5 °C), the medicine administration should not be discontinued. Blood pressure and body temperature are normalized after the end of treatment.

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

## **5. HOW TO STORE ADAPTOL**

*Adaptol 500 mg Tablets:*

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

*Adaptol 300 mg Hard Capsules:*

Do not store above 25°C. Store in the original package in order to 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 “EXP”. 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).

The other ingredients are methylcellulose, calcium stearate.

Capsule shell components: titanium dioxide, gelatin.

### **What *Adaptol* looks like and contents of the pack**

*Adaptol 500 mg Tablets:* 10 tablets per blister, 2 blisters (20 tablets) in the carton box.

*Description:* white or almost white, round, flat tablets with bevelled edges and break-mark 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.

*Adaptol 300 mg Hard Capsules:* 10 hard capsules per blister; 2 blisters (20 hard capsules) in the carton box.

*Description:* hard white/white gelatin capsules No. 0 containing white or almost white powder. Presence of conglomerates of particles or powder plug formation is permissible.

### **Marketing Authorisation Holder and Manufacturer**

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