# Paracetamol Adipharm 500 mg tablets paracetamol

## Read all of this leaflet carefully before you start taking this medicine.

This medicine is available without prescription. Still, to get the best results from the treatment, you must follow the instructions for use of this medicinal product.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information .
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

#### What is in this leaflet

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## 1. What Paracetamol Adipharm is and what it is used for

Paracetamol Adipharm is a non-opiate analgesic (relieves pain) and antipyretic (lowers fever). Its has a stronger effect on the central nervous system, and a milder effect on the peripheral nervous system which accounts for its milder anti inflammatory activity compared to non-steroidal antiinflammatory drugs.

Paracetamol Adipharm tablets are indicated to relieve mild to moderate pain including headache, toothache, neuralgia, muscular and rheumatic pain, or post-operative and posttraumatic pain.

Paracetamol Adipharm tablets can be used to relieve muscular and joint pain in cold and flu, and reduce fever in bacterial and viral infections.

#### 2. Before you take Paracetamol Adipharm

#### Do not take Paracetamol Adipharm:

- if you are allergic (hypersensitive) to paracetamol or any of the other ingredients of this medicine;
- if you suffer from a severe liver or kidney disease;
- at the same time with other paracetamol containing drugs, to avoid the risk of overdosing;
- at the same time with drugs for treatment of tuberculosis (rifampicin);
- at the same time with drugs for treatment of bacterial

infections (chloramphenicol);

- at the same time with drugs for treatment of epileptic seizures (barbiturates, antiepileptics).

This medicine should not be given to children under 6 years of age.

#### Take special care with Paracetamol Adipharm

- if, regardless of the treatment, your symptoms persist for more than 5 days or if these symptoms are accompanied by fever, headache, skin rash, nausea and vomiting for more than 3 days, you should stop the treatment and consult your doctor.
- if you are having an operation or even a dental treatment, you must tell your doctor that you are taking paracetamol.
- caution is required when using this product in patients with kidney or liver diseases, and their liver and kidney functions should be monitored.
- caution is required when using this product in frail and exhausted individuals, and also in those suffering from alcohol abuse.

#### Using other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

Concomitant use of Paracetamol with other medicinal products may enhance or weaken their effects:

- Paracetamol may increase the anti-blood clotting effect of some medicines (anticoagulants and fibrinolytics).
- Colestyramine, antacids and the presence of food in the stomach may reduce the absorption of paracetamol.
- Metoclopramide and domperidone increase the absorption rate of paracetamol, and enhance its effects.
- Taking paracetamol at the same time with some medicines like phenytoin, carbamazepine or phenobarbital, may increase the potential for hepatotoxic effects.
- Taking paracetamol at the same time with anti-tuberculosis drugs (isoniazid, etc.) may precipitate severe liver impairment.

#### Taking Paracetamol Adipharm with food and drinks:

No data are available on the necessity of any special dietary regimen or restriction of any foods.

This product should not be taken with alcohol due to a risk of increasing the toxic effect of paracetamol on the liver.



#### Pregnancy and breast-feeding

Please ask your doctor for advice before taking any medicine.

If you are pregnant or breast-feeding, ask your doctor for advice before taking Paracetamol Adipharm.

#### Driving and using machines

Paracetamol Adipharm does not cause any fatigue or dizziness, therefore it can be used during driving and using machines.

### Important information about some of the ingredients of Paracetamol Adipharm

This medicinal product contains lactose, so it should not be used by patients with lactose intolerance.

#### 3. How to take Paracetamol Adipharm

Always take Paracetamol Adipharm exactly as your doctor has told you.

Swallow the tablets with water.

#### Adults and children over 12 years of age:

1-2 tablets every 4-6 hours but not more than 6 tablets a day.

#### Children 6- 12 years:

1/2-1 tablet every 4-6 hours but not more than 4 tablets per 24 hours.

Treatment duration, without consulting a doctor, should not be longer than 5 days for adults and 3 days for children.

### If you take more Paracetamol Adipharm than you should

Seek immediate medical advice if you have taken more than the prescribed dose!

In the event of an overdose liver damage may occur including severe liver failure. In any case of accidental or intentional overdose, seek immediate medical help.

#### If you forget to take Paracetamol Adipharm

If you missed a dose, take your next dose at the normal time without increasing the dose.

#### If you stop taking Paracetamol Adipharm

Do not stop taking Paracetamol Adipharm without first consulting your doctor.

#### 4. Possible side effects

Like all medicines, paracetamol can cause side effects. Side effects are rare if paracetamol is taken at the recommended doses. Nausea and hypersensitivity reactions may occur, particularly skin rash, itching and urticaria (hives). If you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

#### 5. How to store Paracetamol Adipharm

Store below 30°C.

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

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.

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. Further information

#### What Paracetamol Adipharm contains

- The active substance is paracetamol. Each tablet contains 500 mg paracetamol.
- The other ingredients are: sodium starch glycolate (Type A), lactose monohydrate, copovidone, microcrystalline cellulose, magnesium stearate, and talc.

## What Paracetamol Adipharm looks like and contents of the pack

The tablets are white to off-white, round, flat, with a score line on one side.

The tablet can be divided into two equal halves.

The tablets are placed in blister packs, each containing 10 tablets. Each box contains 1 or two blisters (10 or 20 tablets).

#### Marketing Authorisation Holder and Manufacturer

ADIPHARM EAD 130, Simeonovsko shosse Blvd. Sofia 1700, Bulgaria

### This leaflet was last revised in

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