

**Paracetamol Galenika, 120 mg/5 mL, Syrup****paracetamol**

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

Always take this medicine exactly as stated in this leaflet or as your doctor or your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If you feel no improvement or if you feel worse after the period of 3 days, you must contact your doctor.

**In this leaflet:**

1. What Paracetamol Galenika is and what it is used for
2. What you need to know before you take Paracetamol Galenika
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## 1. What Paracetamol Galenika is and what it is used for

Paracetamol Galenika Syrup contains the active substance paracetamol which belongs to the group of analgesics (painkillers) and antipyretics (to lower high body temperature).

Paracetamol Galenika Syrup relieves teething pain, toothache and sore throat, and lowers high body temperature which normally accompanies cold, flu and other infectious diseases affecting children (such as varicella, whooping cough, measles and mumps). The medicine is also recommended after vaccination to lower high body temperature.

## 2. What you need to know before you take Paracetamol Galenika

### Do not give Paracetamol Galenika to your child:

- if your child is allergic (hypersensitive) to paracetamol or to any of the ingredients of this medicine (listed in section 6);
- if your child is taking any other medicines containing paracetamol;
- if your child has a rare hereditary intolerance to some sugars.

### Warnings and precautions

Before you give this medicine to your child, talk to your doctor:

- if your child has liver or kidney problems;
- if your child weighs less than required or is underfed;
- if your child is a premature baby or under 3 months;
- if your child has a **severe infection** because this can increase the risk of **metabolic acidosis**.

Signs of metabolic acidosis include:

- deep, rapid, difficult breathing;
- feeling sick or being sick;
- loss of appetite.

**Talk to your doctor straight away** if your child develops a combination of these symptoms.

### Other medicines and Paracetamol Galenika

Before you give this medicine, make sure to tell your doctor if your child is being given, or has until recently been given, any other medicines, including the medicines that can be bought without a prescription.

Before you give this medicine to your child, make sure to tell your doctor if your child is being treated with any of the following medicines:

- domperidone or metoclopramide (used to relieve the episodes of feeling sick or being sick);
- cholestyramine (used to lower high blood cholesterol);
- warfarin or other medicines to thin the blood;
- any other prescription medicines or child under doctor's supervision.

### Taking Paracetamol Galenika with food, drink and alcohol

Food and drink have no effect on absorption of the medicine.

### Pregnancy and breast-feeding

If you are pregnant, talk to your doctor before you take Paracetamol Galenika Syrup. This medicine can be used while breast-feeding.

## Driving and using machines

Paracetamol Galenika does not affect the psychophysical abilities while driving or using machines.

## Paracetamol Galenika Syrup contains sucrose and liquid sorbitol, non-crystallising

If your child is intolerant to some sugars, tell your doctor before using this medicine.

## Paracetamol Galenika Syrup contains the colour Allura Red AC (E129)

It can cause allergic reactions.

## Paracetamol Galenika Syrup contains methyl parahydroxybenzoate

It can cause allergic reactions, even delayed.

### 3. How to take Paracetamol Galenika

Check the table below to see how much of the medicine to give to your child.

Paracetamol Galenika Syrup is intended for oral use only.

It is very important to **shake the bottle** for at least 10 seconds before use.

Never give more medicine than shown in the table.

Always use the dosage spoon supplied with the pack.

Do not overfill the dosage spoon.

Do not give Paracetamol Galenika with any other paracetamol-containing products.

Always give the lowest effective dose which relieves your child's symptoms.

Child's age: 2 - 3 months	Dose
1. High body temperature after vaccination	2.5 mL (half a dosage spoon)  If necessary, after 4-6 hours, a second 2.5 mL dose may be given
2. Other causes of pain and fever only if your child: - weighs more than 4 kg - is born after 37 weeks	

- Do not give this medicine to babies less than 2 months of age.
- Do not give more than two doses of the medicine.
- Leave at least 4 hours between doses.
- If more than two doses are necessary, talk to your doctor or pharmacist.

Child's age:	Dose of the medicine	Dosing rate over 24 h
3 - 6 months	2.5 mL (half a dosage spoon)	4 times
6 - 24 months	5 mL (one dosage spoon)	4 times
2 - 4 years	7.5 mL (one and a half dosage spoons)	4 times
4 - 8 years	10 mL (two dosage spoons)	4 times
8 - 10 years	15 mL (three dosage spoons)	4 times
10 - 12 years	20 mL (four dosage spoons)	4 times

- Do not give more than 4 doses of the medicine in any 24 hours.
- Leave at least 4 hours between doses.
- Do not give Paracetamol Galenika to your child for more than 3 days, unless your doctor tells you otherwise.

Do not give this medicine to babies less than 2 months of age, unless recommended by your doctor.

Do not give more than the amount recommended above.

If your child feels no improvement or relief of symptoms in 24 hours, seek a doctor's advice.

Long-term use of the medicine can be harmful, unless given under medical surveillance.

This product should be given only if really necessary.

### **If you give more Paracetamol Galenika to your child than you should**

Talk to a doctor at once if your child takes too much of this medicine because of a risk of permanent liver damage.

### **If you forget to give Paracetamol Galenika to your child**

Never give a double dose to your child to make up for a forgotten dose!

### **If you stop giving Paracetamol Galenika to your child abruptly**

Always give Paracetamol Galenika exactly as your doctor or your pharmacist has told you. If you have any further questions on the use of the medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, Paracetamol Galenika can cause side effects, although not everybody gets them.

Very rare cases of serious skin reactions have been reported.

### **Stop giving the medicine and talk to a doctor at once if your child gets any of these side effects:**

Very rare side effects (may affect not more than 1 in 10000 patients taking the medicine)

- allergic reactions like skin rash or itching, occasional difficulty in breathing or swelling of the lips, tongue, throat or face;
- skin rash or peeling of the skin potentially accompanied by lesions in the mouth;
- breathing problem - in children with a history of breathing problems after the use of aspirin or non-steroidal anti-inflammatory drugs (NSAIDs);
- unusual bruising or bleeding;
- changed liver function blood tests.

Other side effects can include seriously low white blood cell counts leading to infection.

### Reporting of side effects

If you get any side effects, you should tell your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine. You can also report side effects to the Medicines and Medical Devices Agency of Serbia (MMDAS):

Medicines and Medical Devices Agency of Serbia  
National Pharmacovigilance Centre  
Vojvode Stepe 458, 11221 Belgrade  
Republic of Serbia  
website: [www.alims.gov.rs](http://www.alims.gov.rs)  
e-mail: [nezeljene.reakcija@alims.gov.rs](mailto:nezeljene.reakcija@alims.gov.rs)

## **5. How to store Paracetamol Galenika**

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

Do not give Paracetamol Galenika after the expiry date which is stated on the inner and the outer packs after Exp. The expiry date refers to the last day of the specified month.

Storage conditions of the unopened medicine: store in original pack for protection against light.

Storage conditions after the first opening: store in original pack for protection against light at the temperatures up to 25°C, for not longer than 28 days.

You should hand the medicines you no longer use to a pharmacy collecting the medicines which are no longer used. Do not throw away the medicines you no longer use via wastewater or household waste. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Paracetamol Galenika contains**

Active ingredient: paracetamol

Content of active ingredient:

5 mL of the syrup contain 120 mg of paracetamol

Other ingredients:

methyl parahydroxybenzoate (E 218); propylene glycol; cellulose, dispersible; xanthan gum; sucrose; liquid sorbitol, non-crystallising (E 420); glycerol; colour Allura Red AC CI 16035 (E 129); cherry aroma 11035-33; water, purified

### **What Paracetamol Galenika looks like and contents of the pack**

#### Appearance:

Paracetamol Galenika Syrup is a homogenous red suspension with cherry aroma.

#### Pack:

Inner pack consists of an amber glass bottle (Type III glass) containing 100 mL of syrup, closed with a polyethylene cap fitted with a safety ring and a transparent liner.

A dosage spoon is made of white polyethylene, 5 ml in volume (with graduated marks at 1.25 mL and 2.5 mL).

Outer pack is a foldable cardboard box containing 1 amber glass bottle with 100 mL of syrup, closed with a polyethylene cap with a safety ring, a polyethylene dosage spoon and a Package Information Leaflet.

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

GALENIKA AD BEOGRAD, Batajnički drum b.b., Belgrade, Republic of Serbia

### **This leaflet was last approved**

September, 2018

### **Legal category:**

Over-the-counter (OTC) medicine.

### **Number and date of Marketing Authorisation:**

515-01-00441-18-002 of 20 September 2018