

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Phizamol 500 mg Effervescent Tablets

paracetamol

**Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Phizamol Effervescent Tablets are and what they are used for**

Phizamol Effervescent Tablets contain Paracetamol, which is a mild pain killer and reduces the body temperature in fever. The tablets are recommended for use in treatment of mild to moderate pain and/or fever.

#### **2. What you need to know before you take Phizamol Effervescent Tablets**

##### **Do not take Phizamol Effervescent Tablets**

- If you are allergic to Paracetamol, or any of the ingredients of this medicine (listed in section 6).

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

Talk to your doctor or pharmacist before taking Phizamol Effervescent Tablets if you:

- Are suffering from liver problems including liver problems due to excessive alcohol consumption.
- Gilbert's syndrome (mild jaundice)
- Are suffering from kidney problems
- Are suffering from dehydration and chronic malnutrition
- Are on long-term treatment with higher doses of Paracetamol.
- Are asthmatics sensitive to Aspirin.
- Are on other Paracetamol containing drugs
- Have fever even after Paracetamol therapy
- Glucose-6-phosphatedehydrogenase deficiency (enzyme deficiency)
- Have hemolytic anemia (abnormal breakdown of red blood cells).

##### **Other medicines and Phizamol Effervescent Tablets**

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

Tell your doctor before you take Phizamol Effervescent Tablets if you are taking:

- Drugs to thin the blood (anti-coagulant drugs e.g. Warfarin ,other coumarins)
- Medicines used to relieve sickness (e.g. Metoclopramide, Domperidone)
- Medicines used to treat high cholesterol (Cholestyramine)
- Probenecid (Medicine used to treat high levels of uric acid in the blood stream(gout))
- Medicine to treat fever or mild pain (Aspirin, Salicylamide)
- Barbiturates and tricyclic antidepressants (to treat depression)
- Medicines used to treat epilepsy (Lamotrigine)
- Medicines to treat tuberculosis (Isoniazid)
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Effects of paracetamol on laboratory tests

Uric acid and blood sugar tests may be affected.

### **Phizamol Effervescent tablets with food, drink and alcohol**

There is no significant effect on absorption of Paracetamol when taken with meal.

### **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.

If necessary, Phizamol Effervescent Tablets can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Paracetamol passes into breast milk. Therapeutic doses of Paracetamol can be administered during breast-feeding.

### **Driving and using machines**

Paracetamol has no influence on the ability to drive and use machines.

### **Important information about the some of the ingredients of Phizamol Effervescent Tablets**

This medicine contains 100 mg sorbitol in each tablet.

This medicine contains 418.5 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 20.92 % of the recommended maximum daily dietary intake of sodium for an adult.

The maximum daily dose of this product is equivalent to 125.55% of the WHO recommended maximum daily intake for sodium. Phizamol Effervescent Tablets is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

## **3. How to take Phizamol Effervescent Tablets**

This presentation is reserved for use in adults and in adolescents aged 12 years and above.

Pediatric patients:

- Children below 12 years of age: Do not give to children younger than 12 years.
- Adolescents of 12 to 15 years and weighing 41 to 50 kg, the posology is one tablet per dose, repeated every 4-6 hours if necessary, without exceeding 4 tablets daily.
- Adolescents of 16 to 18 years and weighing more than 50kg: as adults.

#### Adults:

The usual adult dose is one to two tablets of 500mg, repeated every 4-6 hours, up to a maximum of 6 tablets (3000 mg) in 24 hours.

#### Maximum daily dose:

- The maximum daily dose of Paracetamol must not exceed 3g.
- Maximum single dose is 1g (2 effervescent tablets)

If the pain persists for more than 5 days or the fever lasts for more than 3 days, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

If complaints persist or worsen, you should seek medical advice.  
Do not exceed the stated dose. Cap contains desiccant. Do not eat.

Phizamol Effervescent Tablets could be taken with or without food and drinks.  
If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **If you take more Phizamol Effervescent Tablets than you should:**

If you or someone you know accidentally takes more than the stated dose (an overdose) you should contact a doctor immediately even if you feel well, because there is risk of delayed, serious liver damage.

#### **If you forget to take Phizamol Effervescent Tablets :**

If you forget to take a dose, take another as soon as you remember, unless it is almost time for your next dose. Remember to leave at-least four hours between doses. Never double-up on a dose to make up for the one you have missed.

### **4. Possible side effects**

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

#### **Rare side effects (may affect up to 1 in 1,000 people):**

Allergies, red or purple spots on the skin (purpura), feeling of general discomfort (malaise), drug interaction, oedema (abnormal accumulation of fluid under the skin), abnormal vision, simple skin rash or urticaria (dark red rash on the skin), haemorrhage (bleeding), abdominal pain, diarrhoea, nausea, vomiting, dizziness, fever, sedation,, liver failure, hepatic necrosis (death of liver cells), jaundice, overdose and poisoning, tremor, headache, depression, confusion, hallucinations, sweating, pruritus (itching),).

#### **Very rare side effects (less than 1 in 10,000 patients):**

Hepatotoxicity (damage caused to the liver due to chemicals), abnormal liver function, hypersensitivity reaction requiring discontinuation of treatment (immediate severe allergic reaction), angioedema (swelling on the face, mouth, hands, anaphylactic shock (severe allergic reaction), bronchospasm\*, thrombocytopenia (reduced platelet count), leucopenia (decrease in white blood cells), agranulocytosis (decrease in neutrophils in the blood), hemolytic anemia (abnormal breakdown of red blood cells), hypoglycemia (low levels of blood glucose in the blood), cloudy urine, kidney disorders, renal alteration

(severe renal impairment, nephrite interstitial (kidney disorder), haematuria (blood in urine), anuresis (inability to urinate). Very rare cases of serious skin reactions have been reported.

Other adverse reactions of paracetamol whose frequency cannot be estimated from available data are: toxic epidermal necrolysis (life-threatening skin disorder), erythema multiforme (allergic reaction or infection of skin), Stevens–Johnson syndrome (a severe life-threatening skin disorder), accumulation of fluid in the larynx, , gastrointestinal effects (stomach ulcers and bleeding) and uneasiness.

\*There have been cases of difficulty breathing, wheezing, coughing, and shortness of breath with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs such as ibuprofen.

### **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

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Phizamol Effervescent Tablets**

- Keep this medicine out of the sight and reach of children.
- Do not use Phizamol Effervescent Tablets after expiry date which is stated on the label after EXP. The expiry date refers to last day of that month.
- Store below 30°C. Keep the polypropylene tube tightly closed. Store in the original container to protect from moisture and light.
- Do not use this medicine if you notice visible signs of deterioration, like brown or black spots on the tablets, bulging of tablets or discoloration of the tablets.
- 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 to protect the environment.

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

### **What Phizamol Effervescent Tablets contains:**

The active substance is Paracetamol. Each effervescent tablet contains 500 mg of Paracetamol.

The other ingredients are;

Citric acid, Sodium hydrogen carbonate, Sorbitol E420, Sodium carbonate anhydrous, Povidone K25 (E1201), Simethicone, Saccharin sodium, Lemon flavour (containing maize maltodextrin, acacia gum (E 414), alpha-tocopherol (E 307), Macrogol 6000

### **What Phizamol Effervescent Tablets looks like and content of the pack:**

Phizamol 500 mg Effervescent Tablets are white to off white round, flat, beveled edged plain on both sides.

Polypropylene tube pack: Phizamol 500 mg Effervescent Tablets are packed in white opaque plain polypropylene tube and white opaque tamper evident polyethylene cap with inbuilt desiccant containing 24 tablets, 20 tablets, 10 tablets or 8 tablets.

Pack size: 60 (3 x 20) tablets per carton, 20 (1 x 20) tablets per carton, 10 (1 x 10) tablets per carton, 16 (2 x 8) tablets per carton, 30 (3 x 10) tablets per carton, 24 (3 x 8) tablets per carton, 100 (5 x 20) tablets per carton and 24(1x24) tablets per carton.

Pack size(s) for tube pack: 20 tablets in a tube

10 tablets in a tube  
8 tablets in a tube  
24 tablets in a tube

**Strip packs:**

Pack Size: 4 tablets per carton  
8 tablets per carton  
10 tablets per carton  
16 tablets per carton  
20 tablets per carton  
24 tablets per carton  
30 tablets per carton  
32 tablets per carton  
60 tablets per carton  
100 tablets per carton

Paper/PE/Aluminium/Surllyn strip:

8's tablets per carton  
10's tablets per carton  
16 tablets per carton  
20 tablets per carton  
24 tablets per carton  
30 tablets per carton  
32 tablets per carton  
60 tablets per carton  
100 tablets per carton

'Not all pack sizes may be marketed'.

**CAUTION:** Cap contains desiccant. Do not eat.

**Marketing Authorisation Holder**

Accord Healthcare Ireland Ltd,  
Euro House,  
Euro Business Park,  
Little Island,  
Cork T45 K857,  
Ireland

**Manufacturer :**

Accord Healthcare Polska Sp.z o.o.,  
ul. Lutomierska 50,  
95-200 Pabianice,  
Poland

Accord Healthcare B.V.,  
Winthontlaan 200,  
3526 KV Utrecht,  
The Netherlands

**This medicinal product is authorized in the Member States of the EEA under the following names:**

<b>Name of Member State</b>	<b>Name of medicinal product</b>
United Kingdom	Paracetamol 500 mg Effervescent Tablets
Finland	Paracetamol Accord 500 mg poretabletti/ brustablett
Ireland	Phizamol 500 mg Effervescent Tablets
Italy	Phizamol 500 mg compresse effervescenti
Poland	APAP ból i gorączka, 500 mg, tabletki musujące
Portugal	Paracetamol Accord
The Netherlands	Paracetamol Accord 500 mg bruistabletten

**The leaflet was last revised in 08/2023**