

# BINOZYT® POWDER FOR ORAL SUSPENSION

Azithromycin 200mg/5ml Powder for Oral Suspension

Consumer Medication Information Leaflet (RiMUP)

## WHAT IS IN THIS LEAFLET:

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## WHAT IS BINOZYT USED FOR?

This medicine is usually prescribed to treat:

- chest infections such as chronic bronchitis, pneumonia
- skin and soft tissue infections
- ear infections (acute otitis media)
- infections of the tonsils, throat (pharyngitis) and sinuses
- urethra and cervix infections caused by chlamydia.

## HOW BINOZYT WORKS?

BINOZYT is an antibiotic which belongs to the group of macrolide antibiotics. It stops the growth of certain bacteria.

## BEFORE YOU USE BINOZYT

### When you must not use it

- if you are allergic (hypersensitive) to azithromycin, erythromycin, other macrolide or ketolide antibiotics or to any of the other excipients of BINOZYT.

### **Pregnancy and lactation**

Tell your doctor or pharmacist if you are pregnant, or are planning to become pregnant or if you are breast-feeding before taking any medicine. You should not use this medicine during pregnancy and when you are breast-feeding unless your doctor has specifically recommended it.

### Before you start use it

Tell your doctor if you have any of the following illnesses before taking this medicine:

- Liver problems: your doctor may need to monitor your liver function or stop the treatment
- Kidney problems: if you have severe kidney problems, the dose may have to be adjusted.
- Nervous (neurological) or mental (psychiatric) problems.
- A certain type of muscle weakness called myasthenia gravis.

Since azithromycin may increase the risk of abnormal heart rhythm please tell your doctor if you have any of the following problems before taking this medicine:

- Heart problems such as a weak heart (heart failure), very slow heart rate, irregular heart beat, or something called “long QT syndrome” (found by an electro-cardiogram)
- Low potassium or magnesium in your blood.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicine. This includes medicines that can be bought without a prescription and herbal medicines. It is especially important to mention before taking this medicine:

- Theophylline (used to treat asthma)
- Warfarin or any similar medicine to prevent blood clots: concomitant use can increase the risk of bleeding.
- Ergot derivatives (used to treat migraine): ergotism (i.e. itching in the limbs, muscle cramps and gangrene of hands and feet due to poor blood circulation) may occur. Concomitant use is therefore not recommended.
- Ciclosporin (used to suppress the immune system to prevent and treat rejection of an organ or bone marrow transplant): if concomitant use is required, your doctor will check your blood levels regularly and may adjust the dose accordingly.
- Digoxin (for heart failure): digoxin levels may increase. Your doctor will check your blood levels.
- Antacids (for indigestion): antacids should not be given together with Binozylt.
- Medicines for irregular heart beat (called anti-arrythmics).
- Nelfinavir (used to treat HIV infections): concomitant use can increase concentrations of azithromycin.

## HOW TO USE BINOZYT?

### - How much to use

The doctor will prescribe the individual dosage which is appropriate for you. It is important that you take your medicine precisely in accordance with the doctor’s instructions. You should check with your doctor or pharmacist if you are not sure.

### **Dosage**

BINOZYT dose is based on body weight of your child and must be determined by your doctor. It is important that you give your child BINOZYT precisely in accordance with the doctor’s instructions. You should check with your doctor or pharmacist if you are not sure. BINOZYT may be taken with or without food. A bitter after-taste can be avoided by drinking fruit juice directly after swallowing.

You should check with your doctor or pharmacist if you are not sure.

For oral use.

### **Taking BINOZYT with medicines for indigestion**

If you need to take a medicine for indigestion, such as an antacid, take your medicines at least one hour before or two hours after the antacid.

### **Patients with kidney or liver problems**

You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

### - When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

### - How long to use it

Always keep taking the medicines until the course is finished, even if you feel better. If you stop taking the medicines too soon, the infection may come back. Also, the bacteria may become resistant to the medicine and will then be more difficult to treat.

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

### - If you forget to use it

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It is important to take your medicine every day. Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

### **- If you use too much (overdose)**

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## **WHILE YOU ARE USING IT**

### **Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Binozyt.

Tell your doctor immediately if you become pregnant while taking this medication.

### **Things you must not do**

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Binozyt to anyone else, even if they have the same symptoms or condition as you.

### **Things to be careful of**

#### **Driving and using machines**

This medicine may cause side effects such as dizziness. This may make you less able to do certain things, such as driving or using machines.

## **POSSIBLE SIDE EFFECTS**

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

Binozyt may cause severe allergy and serious skin reactions. Stop using Binozyt and seek medical assistance immediately if you experience any of the following symptoms: skin reddening, blisters, rash, fever, sore throat or eye irritation.

If you have any of the following

symptoms of a severe allergic reaction stop taking this medicine and **tell your doctor immediately** or go to the casualty department at your nearest hospital:

- sudden difficulty in breathing, speaking and swallowing
- swelling of the lips, tongue, face and neck
- extreme dizziness or collapse
- severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs

If you experience any of the following side effects **contact your doctor as soon as possible:**

- diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation. This is something that can rarely happen after taking antibiotics.
- yellowing of the skin or whites of the eyes caused by liver problems
- inflammation of the pancreas, which causes severe pain in the abdomen and back.
- increased or reduced urine output, or traces of blood in your urine caused by kidney problems
- hypersensitivity, itchy rash, skin rash caused by sensitivity to sunlight
- unusual bruising or bleeding
- irregular or rapid heart beat
- vision impairment
- stomach upset, stomach cramps, feeling sick, diarrhoea, wind
- loss of appetite or taste disturbance
- tiredness, dizziness, headache, tingling of the hands or feet
- indigestion, vomiting
- joint pains
- yeast infections especially of the mouth, infections of the vagina
- nervousness, decreased skin sensitivity, drowsiness, sleeplessness
- ringing in the ear, impaired hearing
- pounding heart beat
- inflammation of the bowel, constipation
- inflammation of the liver, changes in liver enzymes
- chest pain, skin swelling, generally feeling unwell, weakness
- abnormal kidney function test

results, abnormal blood potassium

- reductions in white blood cells
- agitation, a feeling of loss of identity, spinning sensation
- abnormal liver function
- reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness
- muscle weakness (myasthenia gravis)
- if you notice that the child vomits and/or irritability with feeding occurs, contact doctor immediately as it may be due to Infantile Hypertrophic Pyloric Stenosis (IHPS)

If any other side effects occur, tell your doctor or your pharmacist immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## **STORAGE AND DISPOSAL OF BINOZYT**

### **-Storage**

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date.

Store below 30°C in the original package.

### **-Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

## **PRODUCT DESCRIPTION**

### **-What it looks like**

It is a white or off-white coloured powder.

After reconstitution, a white to off white coloured, homogenous suspension exists.

### **-Ingredients**

#### **Active substance**

The active substance is azithromycin monohydrate equivalent to 200 mg

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azithromycin per 5mL

## Inactive ingredients

Sucrose

Xanthan gum

Hydroxypropylcellulose

Anhydrous trisodium phosphate

Anhydrous colloidal silica

Aspartame

Cream caramel

Titanium dioxide

## - MAL NO.

MAL09051572ACZ

## **Manufacturer and Product Registration Holder**

### **MANUFACTURER**

Novartis Pharmaceuticals S.R.L.

Str. Livezeni nr. 7A

540472 Targu-Mures, Romania

### **PRODUCT REGISTRATION HOLDER**

Sandoz Products Malaysia Sdn. Bhd.

Unit 1202, Level 12, Uptown 1,

No. 1, Jalan SS 21/58, Damansara

Uptown, 47400 Petaling Jaya,

Selangor, Malaysia

### **DATE OF REVISION**

Oct 2025

### **SERIAL NUMBER**

NPRA(R2/2)240417/1250