

# BINOZYT<sup>®</sup> FILM-COATED TABLETS

Azithromycin (250 mg and 500 mg)

Consumer Medication Information Leaflet (RiMUP)

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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 that 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 electrocardiogram)
- 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) and colchicine (to treat gout): digoxin and colchicine 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-arrhythmic).
- 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 dose that 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.

## Dose

BINOZYT is taken as a 3-day or 5-day course.

- 3-day course: Take 500 mg (two 250 mg or one 500 mg tablet) once each day
- 5-day course: Take 500 mg on Day 1 (two 250 mg tablets or one 500 mg tablet). Take 250 mg (one 250 mg tablet) on days 2, 3, 4 and 5.

For urethra & cervix infections caused by *Chlamydia*, it is taken as a 1-day course:

1-day course: 1,000 mg (four 250 mg tablets or two 500 mg tablets) as a single oral dose.

For oral use.

Take a glass of water with the medicine.

Take the medicine with food.

## Taking BINOZYT with medicines for indigestion

If you need to take a medicine for indigestion, such as an antacid, take your tablets 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 tablets until the course is finished, even if you feel better. If you stop taking the tablets too soon, the infection may

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come back. Also, the bacteria may become resistant to the medicine and will 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*

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**:

- yeast infections especially of the mouth, infections of the vagina
- 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
- reductions in white blood cells
- reductions in platelet (unusual bruising or bleeding)
- reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness
- hypersensitivity, itchy rash, skin rash caused by sensitivity to sunlight
- nervousness, difficulty sleeping, agitation, aggression, anxiety, hallucination, spinning sensation
- headache, decreased skin sensitivity, drowsiness, sleeplessness
- loss of appetite or taste disturbance
- dizziness, tingling of the hands or feet
- vision impairment, blurred vision
- ringing in the ear, impaired hearing

- pounding heart beat
- irregular or rapid heart beat
- stomach upset, stomach cramps, feeling sick, diarrhoea, wind, indigestion, vomiting
- inflammation of the bowel, constipation
- inflammation of the pancreas, which causes severe pain in the abdomen and back
- yellowing of the skin or whites of the eyes caused by liver problems
- inflammation of the liver, changes in liver enzymes (abnormal liver function)
- joint pains
- muscle weakness (myasthenia gravis)
- increased or reduced urine output, or traces of blood in your urine caused by kidney problems
- chest pain, skin swelling, generally feeling unwell, weakness
- abnormal kidney function test results, abnormal blood potassium
- 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 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.

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Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## DATE OF REVISION

NOV 2022

## SERIAL NUMBER

NPRA(R2/1)190222/57

## PRODUCT DESCRIPTION

- *What it looks like*

### **Binozyt 250 mg film-coated tablets:**

White to off-white, oblong, film-coated tablet and plain on both sides.

### **Binozyt 500 mg film-coated tablets:**

White to off-white, oblong, film-coated tablet, deep break line on one side and score line on other side.

- *Ingredients*

#### Active substance

### **Binozyt 250 mg film-coated tablets:**

The active substance is azithromycin monohydrate equivalent to 250 mg azithromycin.

### **Binozyt 500 mg film-coated tablets:**

The active substance is azithromycin monohydrate equivalent to 500 mg azithromycin.

#### Inactive ingredients

Cellulose, Microcrystalline

Starch

Sodium starch glycolate

Silica, colloidal anhydrous

Sodium lauryl sulphate

Magnesium stearate

Opadry white

- *MAL Number*

### **Binozyt 250mg film-coated tablets**

MAL10100128AZ

### **Binozyt 500mg film-coated tablets**

MAL10100127AZ

## MANUFACTURER AND PRODUCT REGISTRATION HOLDER

#### Manufacturer

Sandoz S.R.L.

Str. Livezeni nr. 7A,

540472 Targu-Mures,

Romania.

#### Product Registration Holder

Novartis Corporation (M) Sdn. Bhd.

Level 18, Imazium,

No. 8, Jalan SS 21/37,

Damansara Uptown

47400, Petaling Jaya

Selangor Darul Ehsan