

PATIENT INFORMATION LEAFLET

AGYCIN

Azithromycin for oral suspension USP 40 mg / ml

Each ml suspension after reconstitution contains:

Azithromycin (as Dihydrate) USP

equivalent to Azithromycin anhydrous 40 mg

Excipients q.s.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What is AGYCIN is and what it is used for
2. Before you take AGYCIN
3. How to take AGYCIN
4. Possible side effects of AGYCIN
5. How to store AGYCIN
6. Further information

1. What AGYCIN is and what it is used for

AGYCIN is one of a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other micro-organisms which include:

- Chronic obstructive pulmonary disease
- Community acquired pneumonia, pharyngitis, tonsillitis
- Uncomplicated skin and skin structure

- Urethritis, cervicitis

2. Before you take AGYCIN

Do not take AGYCIN if you/your child:

- is allergic to AGYCIN or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the ingredients. An allergic reaction may cause skin rash or wheezing.

Take special care with AGYCIN

Your doctor needs to know before you take AGYCIN if you/your child have or have had any of the following:

- Kidney problems
- Heart conditions
- Diabetes
- Liver problems: your doctor may need to monitor your liver function or stop the treatment

Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat, or get dizzy or faint or suffer from any muscle weakness when taking AGYCIN.

Taking other medicines

Tell your doctor before taking or giving AGYCIN if you/your child are taking any of the medicines listed below:

- Ergot or ergotamine
- Warfarin or any similar medicine to prevent blood clots
- Ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- Antacids (for indigestion)
- Digoxin (used to treat heart failure)
- Terfenadine (for hay fever or a skin allergy)

You should always tell your doctor if your child are taking or have recently taken any other medicines including those obtained without a prescription.

Taking AGYCIN with food and drink

AGYCIN is not affected by food or drink.

3. How to take AGYCIN

Always take or give AGYCIN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

AGYCIN suspension is generally used for children under 45 kg.

Children:

The usual dose in children is 10 mg/kg of bodyweight, given as a single daily dose for 3 days.

Body Weight	Day-1	Day-2	Day-3
15-25 kg	5 ml	5 ml	5 ml
26-35 kg	7.5 ml	7.5 ml	7.5 ml
36-45 kg	10 ml	10 ml	10 ml

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

Doctors sometimes prescribe different doses to these. The label on the pack will tell you which dose your child should take. If you are still not sure, ask your doctor or pharmacist.

Always continue with the course of treatment even if your child feels better. If your infection gets worse or you do not start to feel better within a few days or a new infection develops, go back and see your doctor.

How to prepare AGYCIN Suspension

To make 40 ml suspension, add a little water, invert bottle and shake until all the powder is dispersed, then slowly add more water upto the mark on the bottle.

Note: This is generalized dosage pattern. Depending on your medical condition, your doctor may prescribe a different regimen.

Do not change the dosage or stop taking your medication without doctor's approval.

If you/your child take too much AGYCIN they may feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately. Take any remaining medicine with you.

If you forget to take or give AGYCIN

If you forget to take AGYCIN take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking AGYCIN

If your child stops taking AGYCIN too soon, the infection may return. Take AGYCIN for the full time of treatment, even when you/your child begin to feel better.

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

4. Possible side effects

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

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching
- Severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with AGYCIN as this may be a sign of serious bowel inflammation
- Severe skin rash causing redness and flaking

The most common side effects that occur when taking AGYCIN are listed below.

These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you:

Very common side effects:

- Stomach cramps, feeling sick, diarrhoea, wind

Common side effects:

- Dizziness, headache, numbness
- Loss of appetite, taste disturbance, being sick, indigestion
- Visual disturbances, deafness
- Skin rash and /or itching
- Joint pain, Tiredness or weakness

- Low numbers of lymphocytes, higher number of eosinophils, low blood bicarbonate

Uncommon side effects that occur while taking AGYCIN are:

- Yeast infections of the mouth and vagina (thrush)
- Low numbers of leukocytes, low number of neutrophils
- Allergic reactions of various severity, blistering of the skin, mouth, eyes and genitals
- Skin more sensitive to sunlight than normal, reduced sense of touch or sensation
- Feeling nervous, general loss of strength
- Sleepiness or sleeplessness
- Poor hearing or ringing in the ears
- Heart palpitations, chest pain
- Constipation, stomach pain associated with diarrhoea and fever
- Inflammation of the liver (hepatitis), changes in liver enzymes

Rare side effects that occur in less than 1 in 1,000 people taking AGYCIN are:

- Agitation, vertigo, changes in liver function

5. How to store AGYCIN

Keep all medicines out of the sight and reach of children.

Do not take or give this medicine after the expiry date which is stated on the bottle.

Bottles should be Store in dry place, below 30°C. Protect from light.

Use the reconstituted suspension within 5 days.

The reconstituted mixture should be stored in a refrigerator (2°C to 8°C).

6. Further information

What AGYCIN contains

The active substance is azithromycin (40 mg in ml).

Other ingredients are Kyron T-112 BN, Sucrose, Aspartame, Powdarome Peppermint Premium and Xanthan Gum.

What AGYCIN contents of the pack

AGYCIN Suspension comes in the pack of 15 ml HDPE bottle.

Manufacturer & Marketing Authorization Holder

BLISS GVS PHARMA LTD.

102, Hyde Park Saki Vihar Road, Andheri (E), Mumbai - 400 072, INDIA.