Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Azenil® Capsules
Azenil® 200 mg / 5 ml Suspension

Each capsule contains: azithromycin (as dihydrate) 250 mg
Each 5 ml of suspension contains: azithromycin (as dihydrate) 200 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

Azenil 200 mg/5 ml Suspension is intended for children from 6 months of age.
Azenil Capsules is intended for children weighing more than 45 kg.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- For the treatment of infections caused by bacteria susceptible to the preparation in the respiratory tract (bronchitis, pneumonia, sinusitis, pharyngitis and tonsillitis), skin and soft tissue, ear and genital infections caused by *Chlamydia trachomatis*.

Therapeutic group: macrolide antibiotic.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (azithromycin) or to any of the other ingredients in this medicine (see section 6).
- You have a history of allergic reaction to the preparation or to erythromycin or to any other antibiotic from the macrolide or ketolide group.
- You have suffered in the past from jaundice resulting from bile flow obstruction in the liver (cholestatic jaundice) or from hepatic dysfunction that happened with the use of azithromycin.

Special warnings regarding use of the medicine

Do not use this medicine without consulting a doctor before beginning treatment if you:
- have pneumonia.
- have cystic fibrosis.
- have known or suspected bacterial infection in the blood.
- have impaired liver or kidney function.
- have an irregular heartbeat, particularly a problem called QT prolongation.
- have a disease that causes muscle weakness (myasthenia gravis).
- have any other medical problems.
- are pregnant or breastfeeding, plan to become pregnant or breastfeed - see the 'Pregnancy and breastfeeding' section.

Children and adolescents

Azenil 200 mg/5 ml Suspension is intended for children from 6 months of age.
Azenil Capsules is intended for children weighing more than 45 kg.

Drug interactions
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- nelfinavir (for treatment of AIDS), since the combination may increase the levels of azithromycin in the blood.
- anticoagulants (e.g., warfarin) - you should be monitored for coagulation indices.
- digoxin.
- colchicine.
- phenytoin.
- antacids containing aluminum or magnesium.
- hydroxychloroquine or chloroquine, taking these medicines together with Azenil may increase the risk of developing side effects that impact the heart.

Using this medicine and food
Suspension – can be taken with or without food.
Capsules – take one hour before a meal or two hours after a meal.

Pregnancy and breastfeeding
Do not use this medicine before you consult a doctor if you are pregnant or planning to become pregnant.
It is not known if Azenil will harm your unborn baby.
Do not use this medicine before you consult a doctor if you are breastfeeding or plan to breastfeed.
Azenil has been reported to pass into breast milk. Consult your doctor about the best way to feed your baby during treatment with Azenil.

Important information about some of this medicine's ingredients

- The capsule contains lactose – if you have been told by a doctor that you have an intolerance to some sugars, contact the doctor before taking this medicine.
- The suspension contains sucrose – if you have been told by a doctor that you have an intolerance to some sugars, contact the doctor before taking this medicine. Exercise caution when using in diabetic patients.
- Both the capsules and suspension contain sodium.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only.

In adults:
For the treatment of sexually transmitted diseases caused by *Chlamydia trachomatis*, the recommended dosage is 1000 mg as a single dose.

For all other indications, the recommended dosage is 500 mg once daily for 3 days. An alternative to this treatment regimen is to divide it over 5 days, with 500 mg taken once on day 1, then 250 mg once daily on days 2 to 5.

In children:
For children over 45kg body weight and adults, including elderly patients the recommended dosage is 500 mg once daily for 3 days.
In uncomplicated genital infections due to *Chlamydia trachomatis*, the recommended dosage is 1000 mg as a single dose.

In general, the total dose in children is 30 mg/kg – divided into 10 mg/kg once daily for 3 days, or given over 5 days at 10 mg/kg once daily on day 1, then 5 mg/kg once daily on days 2-5.

As an alternative to this dosage, children with acute otitis media can be given a single dose of 30 mg/kg as treatment.

For streptococcal pharyngitis: the recommended dosage is 10 mg/kg or 20 mg/kg once daily for 3 days. Do not exceed a daily dosage of 500 mg daily.

Special populations:
The elderly: The recommended dosage in adults is also used in the elderly. Elderly patients may be more susceptible to development of torsades de pointes – a ventricular arrhythmia, than younger patients.

Renal impairment: No dose adjustment is necessary in patients with mild to moderate renal impairment (GFR 10-80 ml/min). Caution should be exercised when administered to patients with severe renal impairment (GFR < 10 ml/min).

Hepatic impairment: The same dosage as in patients with normal hepatic function may be used in patients with mild to moderate hepatic impairment. Since azithromycin is metabolised in the liver and excreted in the bile, the medicine should not be given to patients suffering from severe liver disease.

Capsules: Take the capsule whole. Do not open the capsule and disperse the contents of the capsule, because the effect of these forms of administration has not been tested.
Do not give the capsule to children weighing less than 45 kg.

Suspension: For children weighing less than 15 kg, the prescribed dose should be measured as accurately as possible.

Instructions for preparation of the suspension:

Package that contains powder (600 mg) for preparation of 15 ml of suspension:
Tap the bottle to loosen the powder.
Add 9 ml of water.
Shake well before each use.

Package that contains powder (900 mg) for preparation of 22.5 ml of suspension:
Tap the bottle to loosen the powder.
Add 12 ml of water.
Shake well before each use.

Do not exceed the recommended dose.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember. However, if it is time for the next dose, skip the forgotten dose and take the next dose as usual. Never take a double dose to make up for the forgotten dose!

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not skip any doses of Azenil or stop taking the medicine, even if you begin to feel better, until you finish your prescribed treatment unless you have a serious allergic reaction or your doctor instructs you to stop taking the medicine (see section 4 'Side effects'). **If you skip doses or do not complete the entire course of treatment with Azenil**, your treatment may not work as well as it should, and it will be harder to treat your infection. Completing the full course of treatment will help lower the risk that the bacteria will become resistant to Azenil.
If the bacteria develop resistance to Azenil, Azenil and other antibiotic medicines may not be effective in the future.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Azenil may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

Stop taking the medicine and see a doctor immediately in the event of:

- Serious allergic reactions. Serious allergic reactions can happen in people taking azithromcyin, the active ingredient in Azenil, even after only 1 dose. Stop the treatment and refer to a doctor right away if you feel one or more of the following symptoms:
    - trouble breathing or swallowing
    - swelling of the lips, tongue or face
    - throat tightness, hoarseness
    - rapid heartbeat
    - fainting
    - skin rash (hives)
    - new onset of fever and swollen lymph nodes

  Stop using Azenil at the first sign of a skin rash and refer to a doctor immediately. A rash may be a sign of a more serious reaction to Azenil.

- Liver damage (hepatotoxicity). Stop using the medicine and refer to a doctor immediately in case of yellowing of your skin or the white part of your eyes, dark-colored urine, nausea or vomiting, abdominal pain or tenderness, fever, weakness, itching, unusual tiredness, loss of appetite, change in the color of your bowel movements. These can be signs of a serious reaction to Azenil (hepatotoxicity).

Refer to a doctor immediately in the event of:

- Serious heart rhythm changes that can be life-threatening, including heart stopping (cardiac arrest), QT prolongation, torsades de pointes - ventricular heart rate disturbance, feeling that your heart is pounding or racing (palpitations), chest discomfort, or irregular heartbeat. Refer to a doctor immediately if you or your child feel a fast or irregular heartbeat, get dizzy or faint. Azenil may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this happening are higher in the elderly, in patients with a family history of prolonged QT interval, in patients with a low blood potassium level, in patients who take certain medicines to control heart rhythm (antiarrhythmics).

- Worsening of myasthenia gravis (a disease that causes muscle weakness).

Antibiotics like Azenil may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems.

- Watery diarrhea, diarrhea that does not go away, or bloody stools. You may experience cramping and a fever. They could appear after you have finished treatment with Azenil.

Common side effects
The most common side effects of Azenil are:

- loose stools or diarrhea
- nausea
- stomach pain
- vomiting
- vaginal inflammation
- rash
- indigestion
- headaches

Additional side effects:
Chest pain, rapid heartbeat, flatulence, black stools, jaundice, inflammation of the kidneys, fungal infection, dizziness, vertigo, somnolence, fatigue, itchiness, photosensitivity, angioedema, constipation, anorexia, inflammation of the small intestine, gastritis, anemia, reduced white blood cell (leukocyte) count, agitation, nervousness, insomnia, fever, facial edema, malaise, pain, cough, pharyngitis, runny nose, eczema, sweating, inflammation of the eye.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the capsules and suspension (powder before reconstitution) below 25˚C.
- Store the prepared suspension (after reconstitution) below 25˚C, and use within 5 days.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
Capsules:
Anhydrous lactose, maize starch, magnesium stearate, sodium lauryl sulphate, gelatin, titanium dioxide.

Suspension:
Sucrose, sodium phosphate tribasic anhydrous, hydroxypropyl cellulose, xanthan gum, artificial flavors: cherry, crème de vanilla and banana.

Azenil Capsules contain lactose:
Each capsule contains 151.55 mg lactose.

Azenil Suspension contains sucrose:
Each 5 ml of suspension contains 3.87 g sucrose.
Azenil Capsules and Azenil Suspension contain sodium.

What the medicine looks like and contents of the pack:
Azenil Capsules: White colored capsule with the words “PFIZER” and “ZTM 250” printed in black ink.
Azenil Suspension: White to off-white colored powder. Each package contains a 10-ml measuring syringe, a 5-ml teaspoon and a cup.

Approved pack sizes:

Azenil Capsules: 6 capsules

Azenil 200 mg/5 ml Suspension:
There are 2 package sizes: A package containing powder (600 mg) to prepare a 15 ml suspension, a package containing powder (900 mg) to prepare a 22.5 ml suspension.

Not all pack sizes may be marketed.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health’s National Drug Registry:
Azenil Capsules: 117.66.29827
Azenil Suspension: 118.26.29828

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