

## Package leaflet: Information for the patient

### Clamelle® 500mg Tablets Azithromycin

**Read all of this leaflet carefully before you take this medicine because it contains important information for you.** Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. This medicine is available without prescription. However, you still need to take Clamelle carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- 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.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse.

#### What is in this leaflet

1. What Clamelle is and what it is used for
2. What you need to know before you take Clamelle
3. How to take Clamelle
4. Possible side effects
5. How to store Clamelle
6. Contents of the pack and other information
7. Important information about chlamydia and other sexual health advice

#### 1. What Clamelle is and what it is used for

The ingredient which makes this medicine work is a ‘macrolide’ antibiotic called azithromycin.

Clamelle is used to treat the sexually transmitted infection (STI) called *Chlamydia trachomatis* in people aged 16 years or over, who have **tested positive** but have **no symptoms** and in treatment of their **sexual partners**.

To buy Clamelle you must have had a positive chlamydia test result and have no symptoms or be a sexual partner of someone who has had a positive chlamydia test result, and have no symptoms. If you have symptoms contact your pharmacist for advice.

#### 2. What you need to know before you take Clamelle

##### **Do not take Clamelle but see a doctor instead if you:**

- are **allergic** to azithromycin, other ‘macrolide’ antibiotics or any of the other ingredients of this medicine (listed in section 6)
- are **under 16 years of age**
- have tested positive and also **have symptoms of chlamydia** such as
  - pain when urinating or having sex
  - unusual vaginal discharge (in women) or discharge from penis (in men)
  - bleeding after sex or between periods (in women)
  - pain below your belly button (in women) or in your testicles (in men)
- symptoms suggestive of other STIs, such as unusual lumps, bumps, blisters or sores around the genital or anal area
- are or may be **pregnant** or are **breast feeding**
- have **liver, kidney or heart problems**
- have **myasthenia gravis**.

**If you have diarrhoea or suffer from stomach problems after taking Clamelle, please see your doctor or pharmacist.**

#### Other medicines and Clamelle

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

**Do not take Clamelle if you are taking any of these other medicines:**

- ergotamine or dihydroergotamine (for migraine or poor blood flow)
- warfarin (to thin the blood)
- disopyramide (for irregular heart beat)
- rifabutin (for tuberculosis)
- ciclosporin (to help prevent rejection of transplanted organs, or for use in arthritis or skin problems)
- digoxin (for heart disorders)
- theophylline (for asthma)
- terfenadine (for hayfever or allergies)
- azithromycin for any other infections e.g. chest, sinuses, ear, skin.

**You can still take Clamelle but may need to take extra care if you are taking these medicines**

- **oral contraceptives** (the 'pill') – if you get sickness or diarrhoea whilst taking Clamelle your 'pill' may not prevent you becoming pregnant. You will need to read the 'pill' instruction leaflet to take the right action. Do not have sex, even with a condom, for seven days after taking Clamelle (see section 3).
- **indigestion remedies** – take Clamelle at least 1 hour before or 2 hours after the indigestion remedy. Clamelle will not work as well if both are taken too close together.
- pimozide (for mental illness)
- nelfinavir (for HIV infection)

If you are taking any regular medication and are unsure, check with your doctor or pharmacist.

### **Pregnancy and breast-feeding**

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.

### **Driving and using machines**

Clamelle can cause dizziness and sleepiness. Make sure you are not affected before you drive or operate machinery.

### **3. How to take Clamelle**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The pack contains two tablets.

Take **both tablets together as a single dose** with a glass of water before you go to bed and at least 2 hours after food or any other drink besides water. If you are sick (vomit) within 3 hours of taking your dose, they might not work properly, so ask your pharmacist or doctor for advice.

**You should not delay treatment.** If you have to wait before taking them, see section 5 for storage conditions.

### **After treatment**

- Contact your doctor, Genito-Urinary Medicine (GUM) clinic or community sexual health clinic if you think you have come into contact with chlamydia again or if symptoms develop.
- Ensure any sexual partners are also tested and treated before you have sex with them, otherwise you are at risk of catching chlamydia again.
- If you, or your partner have been treated for chlamydia **do not have sex** (oral, vaginal, anal or using sex toys), **even with a condom for 7 days after taking Clamelle.**

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

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

Like many medicines, this medicine can cause side effects, although not everybody gets them. However, this is usually with longer courses of azithromycin treatment. Do not be alarmed by this list, you may not experience any of them. If you are worried speak to your pharmacist.

**Contact your doctor or nearest casualty department immediately if you have a rare but serious allergic reaction** such as:

- swelling of the body, face, lips or throat. Very occasionally, these effects may be severe causing shortness of breath, shock or collapse
- skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine ) as they may be signs of a hypersensitivity reaction (drug reaction or rash with eosinophilia and systemic symptoms (DRESS))
- severe skin rash that causes blistering (this can affect the mouth and tongue). These may be signs of a condition known as Stevens Johnson syndrome (SJS), or toxic epidermal necrolysis (TEN).

**Tell your doctor if you notice any of the following side effects** or notice any other effects not listed:

- **Very common** (occurs in more than 1 in 10 users): diarrhoea, stomach pain, feeling sick, wind.
- **Common** (occurs in less than 1 in 10 users): lack of appetite (anorexia), dizziness, headache, sensation of pins and needles or numbness (paraesthesia), changes in your sense of taste, visual impairment, deafness, being sick, indigestion, rash, itchy rash (pruritis), joint pain, tiredness, change in the quantity of the white blood cells and the concentration of bicarbonate in the blood.
- **Uncommon** (occurs in less than 1 in 100 users): reduction in the number of white blood cells, increase in the number of white blood cells, thrush (candidiasis), oral thrush, vaginal infection, pneumonia, fungal infection, bacterial infection, inflammation of the throat (pharyngitis), stomach flu (gastroenteritis), breathlessness, chest pain, wheeze and cough (respiratory disorder), inflammation of the mucous membrane inside the nose (rhinitis), nervousness, having difficulty sleeping (insomnia), reduced sense of touch, feeling drowsy (somnolence), hearing loss or ringing in your ears, ear disorder, 'spinning' sensation (vertigo), palpitations, hot flushes, difficulty breathing, nosebleed, constipation, inflammation of the stomach lining (gastritis), difficulty swallowing, swollen abdomen, dry mouth, belching, mouth ulcer, increased salivary flow, inflammation of the liver (hepatitis) causing yellowing of the skin or eyes or tiredness, pain in abdomen, joint or muscles, sensitivity to sunlight, itchy skin rash caused by allergic reaction - pale or red irregular raised patches with severe itching (urticaria), inflammation of the skin (dermatitis), dry skin, excessive sweating, pain, swelling and reduced motion in your joints (osteoarthritis), muscle pain, back pain, neck pain, painful urination, pain in your kidney, spotting, testicular disorder, face swelling, chest pain, fever, nerve pain, swelling (oedema), general feeling of being unwell, weakness, change in liver enzyme levels and blood levels, post procedural complications.
- **Rare** (occurs in less than 1 in 1,000 users): agitation, restlessness, changes in liver function or jaundice (yellowing of the skin or whites of the eyes), skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid).
- **Not known:** reduction of red blood cells due to destruction (haemolytic anaemia), reduction in number of platelets (thrombocytopenia), inflammation of the lining of large intestine (pseudomembranous colitis, you might get diarrhoea, stomach cramps, fever, blood in the stools), aggression, anxiety, confusion, hallucination, fainting, fits, muscle spasms, changes in smell and taste, disorder characterised by muscle weakness, difficulty chewing or swallowing and slurred speech (myasthenia gravis), changes of the heart rhythm found by an electrocardiogram (QT prolongation and torsade de pointes), rapid or irregular heart beat, low blood pressure, inflammation of the pancreas causing pain and tenderness in the abdomen and back, discoloration of the tongue, liver failure (which has rarely resulted in death) or liver disease, erythema multiforme (raised red patches on the skin which may blister), kidney failure or inflammation (increased need to urinate at night, muscle twitching and cramps, loss of appetite, feeling or being sick, unpleasant taste in mouth).

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for [MHRA Yellow Card in the Google Play or Apple App Store](#).

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

## 5. How to store Clamelle

Keep this medicine out of the sight and reach of children. Store below 25°C (room temperature) in the original package. Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 protect the environment.

## 6. Contents of the pack and other information

### What Clamelle tablets contain

- The active substance is 500mg of azithromycin.
- The other ingredients are calcium hydrogen phosphate (anhydrous), hypromellose, maize starch, pregelatinised starch, microcrystalline cellulose, sodium laurylsulfate, magnesium stearate, polysorbate 80, talc, indigotin (E132) and titanium dioxide (E171).

### What Clamelle looks like and contents of the pack

Pale blue, oblong, biconvex film-coated tablets, with imprint PLIVA on one side and 500 on the other side.

Blisters (PVC/Al foil) packed in a carton box containing 2 tablets.

## 7. More about chlamydia and other important sexual health advice

### What is it?

Chlamydia is an extremely common sexually transmitted infection (STI) caused by a bacteria called *Chlamydia trachomatis* which is found in the semen and vaginal fluids of men and women who have the infection. It infects the neck of womb (cervix) in women, the tube that drains the bladder of urine (urethra) and the back passage (rectum) in both women and men.

Chlamydia affects between 1 in 10 and 1 in 100 people and is most common in people aged 16 to 25 years.

### How do you get it?

Chlamydia is easily passed from one person to another through sexual contact. The infection is most commonly spread through:

- unprotected vaginal, anal or oral sex
- sharing sex toys if you don't wash them or cover them with a new condom each time they're used.

It can also be passed on fingers to your eyes after touching the genital area. A mother can also pass the infection to her baby during childbirth.

### Are there any symptoms?

Chlamydia is a 'silent' condition; as many as 70% of infected individuals have no symptoms, so it can stay hidden for many months or years. Those who do have symptoms may have any of the following:

**In women:** unusual vaginal discharge, a need to pass urine more often, pain when passing urine or during sexual intercourse, pain below the belly button or bleeding between periods or after sex.

**In men:** pain and/or burning when passing urine, discharge from the penis, irritation at the tip of the penis or swelling and pain in the testicles.

**In men and women:** if the infection is in the rectum, there are rarely any symptoms but it may cause discomfort and discharge.

If you have symptoms or you think you may have another infection, consult your doctor or local GUM clinic or community sexual health clinic for further investigation and treatment.

### Why is treatment important?

It is very important to get treated for chlamydia. If left untreated the infection can spread to other parts of the body and develop into more serious problems such as:

**In women:**

- pelvic inflammatory disease which can seriously affect the womb or fallopian tubes
- scarring or damage to the fallopian tubes causing pain or infertility (problems getting pregnant)
- increased risk of ectopic pregnancies (when pregnancy develops outside the womb)
- infection in the liver, causing pain and inflammation.

**In men:**

- painful infection in the testicles and possible reduced fertility.

**In men and women:**

- rarely, inflammation of the joints (reactive arthritis). This is sometimes accompanied by inflammation of the urethra and the eye, when it is known as Reiter's syndrome.

Each time you have chlamydia you are at increased risk of serious problems. If you have already had chlamydia in the last 6 months you should see a doctor. If left untreated you can also infect your partner.

**Can it be prevented?**

Use a condom during sex to reduce the risk of getting or passing on not just chlamydia, but other sexually shared infections, such as HIV, syphilis and gonorrhoea.

If you, or your partner have been treated for chlamydia do not have sex (oral, vaginal, anal or using sex toys), even with a condom for 7 days after taking Clamelle, otherwise you can become re-infected. Avoid using sex toys. If you do share them, wash them or cover them with a new condom before anyone else uses them.

**Other important sexual health advice**

Using a condom will help reduce your risk of getting or passing on chlamydia and other sexually shared infections (STIs).

If you have tested positive for chlamydia, you are also at higher risk of other STIs. It is important that you visit your GUM clinic or community sexual health clinic to be tested for these. Your pharmacist can tell you how to go about this.

If you have tested positive for chlamydia, then it is important that your current sexual partner and any previous, but recent partners are also tested and treated. They should also receive advice from a healthcare professional. There are a number of ways that partners can be contacted confidentially- your pharmacist can tell you how to go about this. You are strongly advised to tell your partner(s), but it is not compulsory.

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This leaflet was last revised in January 2018