

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CLAMELLE 250 mg (Capsules)

Azithromycin dehydrate

Contains sugar: Lactose anhydrous 141,60 mg

Read all of this leaflet carefully before you start taking CLAMELLE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CLAMELLE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

1. What CLAMELLE is and what it is used for

For the treatment of:

Adults:

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Anisa Suliman

- Mild to moderate infections caused by susceptible organisms. In lower respiratory tract infections including bronchitis due to *Haemophilus influenza*, *Moraxella catarrhalis*, *Streptococcus pneumoniae* or *Staphylococcus aureus* and pneumoniae due to *Streptococcus pneumoniae* or *Haemophilus influenza*.
- Uncomplicated skin and soft tissue infection.
- Sinusitis due to *Haemophilus influenza*, *Streptococcus pneumoniae* or *Staphylococcus aureus*. As an alternative to first line therapy of pharyngitis/tonsillitis.
- Uncomplicated genital infections due to *Chlamydia trachomatis* in men and women with sexually transmitted diseases.

Children (5 years of age and over):

- Acute otitis media and pharyngitis/tonsillitis caused by susceptible organisms in children.

2. What you need to know before you take CLAMELLE

Do not take CLAMELLE:

- if you are allergic to CLAMELLE or any other macrolide antibiotics such as erythromycin or clarithromycin. An allergic reaction may cause skin rash or wheezing,
- if you have liver problems,
- if you are taking ergot derivatives such as ergotamine (used to treat migraines),
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with CLAMELLE:

Your doctor needs to know before you take CLAMELLE if you have or have had any of the following conditions:

- Kidney problems.
- Heart conditions.

The following conditions have been reported with the use of CLAMELLE:

- Serious allergic reactions (such as anaphylaxis angioedema, fever, eosinophilia, and skin eruptions).
- Pseudomembranous colitis (inflammation, swelling and irritation of the large intestine).
- Super-infections that is not sensitive to CAMELLE.

Ergotism, or ergot poisoning may be possible (symptoms of poisoning include nausea, vomiting, muscle pain and weakness, numbness, itching, and rapid or slow heartbeat) if CLAMELLE is used with ergotamines (see “Do not take CLAMELLE”)

Other medicines and CLAMELLE

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Please inform your healthcare professional if you are taking:

- Antacids (for indigestion), CAMELLE should be taken one hour before or two hours after antacids. Antacids, aluminium- and magnesium-containing- antacids may decrease the amount of azithromycin in the blood, which may decrease its effects.
- Ergot or ergotamine.
- Astemizole (antihistamine for hay fever).

- Carbamazepine and valproate (used for epilepsy).
- Cyclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow).
- Digoxin (used to treat heart failure).
- Terfenadine (for hay fever or a skin allergy).
- Theophylline (used to treat asthma).
- Triazolam (used for sleeping problems).
- Warfarin or any similar medicine to prevent blood clots.

CLAMELLE with food

You should take CLAMELLE either 1 hour before a meal or 2 hours after a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Azithromycin has not been studied in pregnant women and it is not known whether azithromycin passes into breast milk.

CLAMELLE must not be used during pregnancy or when breastfeeding.

Driving and using machines

It is not always possible to predict to what extent CLAMELLE may interfere with the daily activities of a patient. However, the possibility of side effects like dizziness, sleepiness, tiredness, and fits or fainting should be considered when performing these activities (see “Possible side effects”).

You should ensure that you do not engage in the above activities until you are aware of the measure to which CLAMELLE affects you.

CLAMELLE contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take CLAMELLE

Do not share medicines prescribed for you with any other person.

Always take CLAMELLE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take the recommended dose at least 1 hour before, or 2 hours after a meal.

For sexually transmitted diseases caused by *Chlamydia trachomatis*:

- A single dose of 1 g azithromycin.

Other infections:

- Adults and children, 16 years and over: A total dose of 1,5 g which should be given as 500 mg daily for 3 days or alternatively an initial single oral dose of 500 mg on day 1, then 250 mg as a single daily dose for 4 days.

Children, 45 kg and over: Dose as for adults.

Elderly persons: The normal adult dosage is recommended.

If you have the impression that the effect of CLAMELLE is too strong or too weak, talk to your doctor or pharmacist.

If you take more CLAMELLE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CLAMELLE

If you forget to take CLAMELLE 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 individual dose.

If you stop taking CLAMELLE

If you stop taking CLAMELLE too soon, the infection may return. Take the capsules for the full time of the treatment, even when you 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

CLAMELLE can have side effects.

Not all side effects reported for CLAMELLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLAMELLE, please consult your health care provider for advice.

If any of the following happens, stop taking CLAMELLE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

These are all very serious side effects. If you have them, you may have had a serious reaction to CLAMELLE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- Stomach upset, stomach cramps, feeling or being sick, diarrhoea, loss of appetite, wind, loose stools, constipation, indigestion, bloody stools, taste disturbance.
- Reduction in white blood cells.
- Headache, dizziness, or vertigo (spinning feeling).
- Poor hearing or ringing in the ears.
- Fits or fainting.
- Sleepiness, tiredness, or weakness.
- Numbness or pins and needles.

Less Frequent

- Anaphylaxis (severe, potentially life-threatening allergic reaction) and angioedema (painless swelling under the skin, triggered by an allergy).
- Skin rash and/or itching; severe skin rash causing redness and flaking (conditions such as Erythema multiforme, Steven's-Johnson syndrome, toxic epidermal necrolysis).
- Rapid or irregular heartbeat and chest pain.
- Inflammation of the bowel (Pseudomembranous colitis).
- Inflammation of the pancreas (pancreatitis).
- Inflammation of the kidney (fever, skin rash and painful joints) or kidney failure.
- Inflammation of the liver (hepatitis), changes in liver enzymes, yellowing of the skin or eyes (jaundice) or liver failure (rarely life-threatening).

Frequency unknown

- Soreness or itching of the vagina (vaginitis).
- Temporary deafness.
- Skin more sensitive to sunlight than normal.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CLAMELLE.

5. How to store CLAMELLE

Store all medicines out of reach of children.

Store below 25 °C in well-closed container.

There are no special storage instructions for CLAMELLE.

Do not use after the expiry date printed on the carton and blister.

The expiry date refers to the last day of that month.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What CLAMELLE contains

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The active ingredient is azithromycin dehydrate.

The other ingredients are:

- *Capsule content:* Colloidal Silicon Dioxide; Lactose anhydrous; Magnesium stearate; Maize Starch; and Sodium Lauryl Sulphate.
- *Capsule shell:* Gelatine (Cap & Body); Blue Cap {Brilliant Blue (C. I. No. 42090); Titanium Dioxide (C.I. No. 77891); Methyl Paraben; and Propyl Paraben}; and White Body {Titanium Dioxide (C.I. No. 77891); Methyl Paraben; and Propyl Paraben}.

What CLAMELLE looks like

White coloured powder filled in hard, gelatine opaque capsule size “0” with blue cap and white coloured body.

Blister strips of 4 or 6 capsules.

Holder of Certificate of Registration

STRIDES PHARMA (SA) (Pty) LTD

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South Africa

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