

- Change in the sense of smell and taste
- Headache, dizziness, fear of heights, anxiety, difficulty sleeping, bad dreams, confusion, disorientation, hallucinations (seeing things), changes in mood or behaviour and change in sense of reality.
- Hearing loss, 'ringing' in the ears
- Changes in heart rhythm
- A blood test may show an increase in liver enzymes.
- Muscle or joint pain
- Genital 'thrush'
- Low blood sugar
- On rare occasions clarithromycin can cause liver and gall bladder problems
- Inflammation of the kidneys, and kidney failure have been reported rarely
- Convulsions (fits) have been reported rarely
- Inflammation of the pancreas and low levels of white blood cells have been reported rarely
- Inflammation of the eye has been reported very rarely, usually in patients also taking rifabutin.

**If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

#### Reporting of side effects

If you get any side effects, talk to your doctor or 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. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. HOW TO STORE CLARITHROMYCIN TABLETS

Keep out of reach and sight of children.

Do not use after the expiry date which is stated on the pack.

#### 6. FURTHER INFORMATION

##### What Clarithromycin tablets contain

Each tablet contains 250mg or 500mg of the active ingredient clarithromycin.

The other ingredients are: Croscarmellose sodium, starch pregelatinised, silicon dioxide, povidone, stearic acid, magnesium stearate, talc, microcrystalline cellulose, polyethylene glycol.

Coating: Quinoline Yellow Aluminium Lake (E104), Vanillin, Propylene Glycol (E1520), Hydroxypropyl Cellulose, Sorbic acid (E200), Titanium Dioxide (E171), Hypromellose (E464), Polysorbate 80 (E433).

##### What Clarithromycin Tablets look like and contents of the pack

Clarithromycin tablets are yellow, elliptical, biconvex film-coated tablets with a smooth surface.

Each pack contains 10, 12, 14, 20, 30, 50, or 500 tablets in blister packs.

Not all pack sizes may be marketed.

##### Marketing authorisation holder

Strandhaven Limited t/a Somex Pharma, Ilford, Essex, IG3 8BS, UK.

##### Manufacturer:

Strandhaven Limited t/a Somex Pharma, Ilford, Essex, IG3 8RA, UK.

##### Other sources of information:

**To request a copy of this leaflet in braille or large print please call, 020 8590 9399 (UK Only).**

**Leaflet last approved: February 2024**

4

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#### PACKAGE LEAFLET: INFORMATION FOR THE USER

##### Clarithromycin 250mg film coated tablets Clarithromycin 500mg film coated tablets

#### 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 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 Clarithromycin tablets are and what they are used for
2. Before you take Clarithromycin tablets
3. How to take Clarithromycin tablets
4. Possible side effects
5. How to store Clarithromycin tablets
6. Further information

#### 1. WHAT CLARITHROMYCIN TABLETS ARE AND WHAT THEY ARE USED FOR

Clarithromycin is an antibiotic belonging to a group of medicines known as the macrolides. Antibiotics stop the growth of bacteria that cause infections.

Clarithromycin tablets are used to treat:

- Chest infections such as bronchitis and pneumonia
- Throat and sinus infections
- Skin and soft tissue infections
- Infections in patients with duodenal ulcer.

#### 2. BEFORE YOU TAKE CLARITHROMYCIN TABLETS

##### Do NOT take Clarithromycin tablets, and tell your doctor if:

- you are hypersensitive (allergic) to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or to any of the ingredients in the tablets (listed in section 6)
- you are taking a medicine containing lomitapide
- You have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)
- you are taking any of the following medicines (ask your doctor for advice on alternative medicines):
  - ergotamine or dihydroergotamine tablets or use ergotamine inhalers (for migraine)
  - colchicine (usually taken for gout) as this can also cause serious side effects
  - the following which can sometimes cause serious disturbances in heart rhythm if taken with clarithromycin
    - terfenadine or astemizole (for hay fever or allergies)
    - cisapride (for stomach disorders)
    - pimozone (for treatment of some mental conditions).
    - Ivabradine (for Symptomatic treatment of chronic stable angina pectoris)

**Use of Clarithromycin tablets is not recommended for children younger than 12 years.**

##### Take special care with Clarithromycin tablets

##### Tell your doctor or pharmacist if:

- you have any kidney or liver problems
- you have used Clarithromycin before on several occasions or for a long time

1

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**Taking other medicines**

- Clarithromycin may occasionally interfere with other medicines.
- Hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as clarithromycin may increase the chance of you getting abnormal heart rhythms and other serious side effects that affect your heart.
- Corticosteroids, given by mouth, by injection or inhaled (used to help suppress the body's immune system – this is useful in treating wide range of conditions)

**Do not take Clarithromycin tablets** with ergotamine, dihydroergotamine, colchicine, terbinafine, astemizole, cisapride, ivabradine, ticagrelor, ranolazine or pimozone (see 'Do Not take' at the beginning of section 2).

**It is important to tell your doctor or pharmacist if you are taking any of the following medicines:**

- Theophylline (used to treat asthma)
- Warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to thin your blood)
- Digoxin, quinidine or disopyramide (for heart problems)
- Carbamazepine (for epilepsy).
- Zidovudine or ritonavir (used in HIV patients).
- Omeprazole, antacids or ranitidine (used in stomach disorders)
- Ciclosporin (used in organ transplants)
- Ibrutinib (for cancer treatment)
- Bromocriptine (for Parkinson's disease)
- Macrolide antibiotics such as erythromycin and clindamycin
- Certain medicines that are broken down in the body in a similar way to clarithromycin. When taken with clarithromycin, their effects may be increased. These include:
  - triazolam, midazolam, alprazolam or hexobarbital (sedatives)
  - lovastatin or simvastatin (for high cholesterol)
  - rifabutin or rifampicin (for treatment of some infections)
  - phenytoin or valproate (for epilepsy)
  - tacrolimus (used after organ transplants)
  - methyl prednisolone, vinblastine (for certain types of cancer)
  - sildenafil (for impotence)
  - alfentanil (general anaesthetic)
  - cilostazol (improves blood circulation in the legs)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

**Pregnancy and Breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding do not take Clarithromycin tablets without consulting your doctor first.

**Driving and using machines**

At the recommended doses, Clarithromycin is not known to affect the capacity to drive or use machines. However, you may experience dizziness or vertigo as a possible side effect. If affected you should not drive or operate machines.

**3. HOW TO TAKE CLARITHROMYCIN TABLETS**

Your doctor will tell you how to take Clarithromycin tablets and for how long. Do not stop taking Clarithromycin tablets early. It is important to take the tablets for as long as the doctor has told you to, otherwise the infection might come back.

**For chest, throat or sinus infections, soft tissue and skin infections**

Adults and children over 12 years: The usual dose is 250mg twice a day for 6-14 days. Your doctor may increase the dose to 500mg twice daily for up to 2 weeks, for severe infections

Children younger than 12 years: Use Clarithromycin paediatric suspension.

2

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**For treatment of infection associated with duodenal ulcers**

Adults, including the elderly:

There are a number of effective treatment combinations available in which Clarithromycin Tablets are taken with one or two other medicines:

**Triple Therapy (7-14 days)**

Clarithromycin 500mg, lansoprazole 30mg and amoxicillin 1000mg, twice daily for 7 – 14 days.

**Triple Therapy (7 days)**

Clarithromycin 500mg, lansoprazole 30mg and metronidazole 400mg, twice daily for 7 days.

**Triple Therapy (7 days)**

Clarithromycin 500mg, omeprazole 40mg daily and amoxicillin 1000mg or metronidazole 400mg, twice daily for 7 days.

**Triple Therapy (10 days)**

Clarithromycin 500mg and amoxicillin 1000mg twice daily and omeprazole 20mg daily, for 10 days.

**Dual Therapy (14 days)**

The usual dose of Clarithromycin is 500mg three times daily with omeprazole 40mg once daily, for 14 days.

Patients with severe kidney problems:

The doctor may reduce the dose of Clarithromycin tablets.

Your doctor will decide which treatment combination is best for you. If you are unsure which tablets you should be taking or for how long, please ask your doctor for advice.

**If you take more Clarithromycin tablets than you should**

If you take more Clarithromycin tablets than you should, contact a doctor or pharmacist immediately. An overdose is likely to cause vomiting or stomach pains.

**Remember to take your medicine.****If you forget to take Clarithromycin tablets**

If you forget to take Clarithromycin tablets do not take a double dose to make up for missed individual doses. Take one as soon as you remember and continue with the prescribed treatment as usual.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Clarithromycin tablets can cause side effects, although not everybody gets them.

**Stop taking the tablets and contact your doctor immediately if any of the following occur:**

- Severe or prolonged diarrhoea, which may have blood or mucous in it, during or after treatment with Clarithromycin tablets.
- Feeling unwell, yellowing of the skin and /or eyes (jaundice), or pale stools with dark urine. Very rarely liver failure can occur which may be fatal.
- Difficulty in breathing, fainting and swelling of the face, lips and throat. You may have a serious allergic reaction and need urgent medical attention.
- Skin rashes, which may range in severity from mild itchy rash, swelling and skin eruptions to a rare condition called Stevens-Johnson reaction (severe illness with ulceration of the skin, mouth and eyes).
- Fever and sloughing of the skin caused by a severe allergic reaction (toxic epidermal necrosis).

**Other side effects may occur, some of which could be severe, in which case tell your doctor immediately.**

**These include:**

- Feeling sick, vomiting, indigestion, pain, and diarrhoea
- Swelling of the mouth or tongue, thrush, tongue discolouration, and rarely tooth discolouration

3

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