What is in this leaflet:

1. What Clarithromycin is and what it is used for
2. What you need to know before you take Clarithromycin
3. Possible side effects
4. How to store Clarithromycin
5. Contents of the pack and further information

What Clarithromycin is and what it is used for:

Clarithromycin is an antibiotic belonging to a group called the macrolides. Antibiotics stop the growth of bacteria which cause infections.

Clarithromycin is used to treat infections such as:
- Chest infections such as bronchitis and pneumonia
- Throat and sinus infections
- Ven and tissue infections
- Bacterial skin infections
- Helicobacter pylori infection associated with duodenal ulcer

Possible side effects:

Some possible side effects may occur but do not usually mean you have to stop taking Clarithromycin.report these side effects to your doctor.

How to take Clarithromycin:

1. Do not take Clarithromycin if you:
   - are allergic to clarithromycin or any macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients of this medicine (listed in section 6).
   - have liver or kidney problems. If you develop symptoms of hepatic disease such as anorexia, yellowing of the skin (jaundice), dark urine, pruritus or tender abdomen, please stop taking Clarithromycin and inform your doctor immediately (see section 4 Possible side effects).
   - you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including tachycardia of paroxysmal or abnormality of electrocardiogram (ECG, electrical recording of the heart) called 'long QT syndrome'.
   - have abnormally low levels of potassium or magnesium in your blood.
   - are taking ergotamine or dihydroergotamine tablets (for migraines), terfenadine or astemizole (for hay fever or allergy), as combining these drugs with clarithromycin can sometimes cause serious disturbances in heart rhythm.
   - are taking other medicines which are known to cause serious disturbances in heart rhythm.

Consult your doctor for advice on alternative medicines.

You will need to take a test to check these levels before you start taking this medicine.

2. Taking Clarithromycin:
   - Talk to your doctor or pharmacist before taking Clarithromycin.
   - Have your blood pressure checked (for high blood pressure and diabetes).
   - You may need to have your blood pressure checked (for high blood pressure and diabetes).
   - Call your doctor immediately if you have any of the side effects listed above.

Warnings and precautions:

1. Talk to your doctor or pharmacist before taking Clarithromycin.
   - Methylprednisolone (a corticosteroid).
   - Vincristine (for treatment of cancer).
   - Methylprednisolone (a corticosteroid).
   - Vincristine (for treatment of cancer).

Other medicines and Clarithromycin:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of these medicines. This is especially important if you are taking the following medicines:

- Depo-provera (for contraception).
- Triamcinolone (for respiratory diseases).
For infections caused by certain types of bacteria
called mycobacteria:
The usual dose is 500 mg twice daily. Your doctor may
increase the dose to 1000 mg twice daily if the response is
slow after 4 weeks. For the prevention of mycobacterial
infections, the usual dose is 500 mg twice daily.

For the treatment of Helicobacter pylori infection
associated with duodenal ulcers:
The number of effective treatment combinations available
in which Clarithromycin is taken together with one
or two other drugs. These include the following:
• Triple Therapy (7 days)
  Clarithromycin 100 mg twice daily together with
  omeprazole 20 mg twice daily and a proton pump
  inhibitor at the recommended daily dose for 7 days.
• Triple Therapy (7-10 days)
  Clarithromycin 500 mg twice daily together with
  omeprazole 20 mg twice daily and a proton pump
  inhibitor at the recommended daily dose for 7-10 days.
• Dual Therapy (14 days)
  Clarithromycin 500 mg twice daily for 14 days
  together with omeprazole 40 mg once daily.
• If you take Clarithromycin tablets that you should be taking, or if
  you take Clarithromycin tablets that you should not be taking, please
  consult your doctor for advice.

If you take more Clarithromycin Tablets than you should
If your symptoms or side-effects worries you, tell your
physician or pharmacist. If you think you have
overdosed, contact your doctor, physician or pharmacist immediately.

If you forget to take Clarithromycin
If you forget to take a dose, take another as soon as you
remember. If it is more than 12 hours since your
last dose, then do not take the missed dose:
• 250 mg tablets: Yellow, oval-shaped, convex film-coated
  tablets scored on one side.
  • 500 mg tablets: Yellow, oval-shaped, convex film-coated
  tablets scored on one side.
  • 625 mg tablets: Yellow, oval-shaped, convex film-coated
  tablets scored on one side.

Taking into consideration the medical and
manufacturing history of Clarithromycin, it is
likely that this medicine can cause a rare
hypersensitivity skin reaction, rash with
blisters, and swelling of the face and lips.

Common side effects
(1 and 10 every 100 people are likely to get these):
• stomach pains such as feeling or being sick, stomach
  pain, indigestion or diarrhoea.
• headache, changes in sense of taste.
• rash, redness, sensitisation (as seen in blood tests).
• swelling, indigestion, diarrhoea.
• abnormal colour of the urine and abnormal levels of a
  marker for kidney function.
• accelerated (tachycardia) or irregular heart beat (Torsades
de pointes).
• pain, indigestion or diarrhoea.
• feeling unwell (asthenia), feeling tired, pain in the chest
  and feeling cold (chills).
• stiffness, aches or pains in the muscles.
• kidney problems such as raised levels of protein normally
  excreted by the kidneys or raised levels of kidney
  enzymes.

Possible side effects
•  liver disorders (hepatitis and cholestasis).
•  increased amounts of certain substances in the blood
  (transaminases, alkaline phosphatase and lactate
  dehydrogenase).
•  inflammation of the lining of the stomach or oesophagus
  (Gastroduodenitis).
•  digestive problems such as constipation, belching,
  diarrhea, mouth or anal pain.
•  irregular heart beat (arrhythmias) and palpitations.
•  fainting, dizziness, drowsiness, tremors, involuntary
  movements of the limbs (extrapyramidal).
•  loss of appetite (anorexia).
•  low concentration of leucocytes and neutrophils (types of
  white blood cells).
•  changes in sense of taste.
•  headache, change in the way things taste or smell.
•  changes in liver enzymes (as seen in blood tests).
•  stomach problems such as feeling or being sick, stomach
  pain, indigestion or diarrhoea.
•  rare cases, difficulty in breathing, fainting and swelling of
  the face, lips, tongue and throat.
•  loss of ability to taste and smell things.
•  allergic reactions including rashes have been reported
  (erythema multiforme).
•  headache or fever.

Frequency not known (cannot be estimated from the available
data):
•  severe inflammation of the bowel (pseudomembranous
colitis) linked to antibiotic use.
•  severe skin infections, erythema multiforme.
•  dapsone reaction (nausea, depression, dilution of urine).
•  dapsone reaction (nausea, depression, dilution of urine).
•  abnormal colour of the urine and abnormal levels of a
  marker for kidney function.
•  abnormal urination problems and abnormal levels of a
  marker for kidney function.
•  kidney problems (nephritis) and kidney failure.
•  rash, redness, sensitisation (as seen in blood tests).
•  low concentration of leucocytes and neutrophils (types of
  white blood cells).
•  changes in sense of taste.
•  headache, change in the way things taste or smell.
•  changes in liver enzymes (as seen in blood tests).
•  stomach problems such as feeling or being sick, stomach
  pain, indigestion or diarrhoea.
•  rare cases, difficulty in breathing, fainting and swelling of
  the face, lips, tongue and throat.
•  loss of ability to taste and smell things.
•  allergic reactions including rashes have been reported
  (erythema multiforme).
•  headache or fever.

References
Clarithromycin may worsen the symptoms of myasthenia
gravis (a condition in which the muscles become weak and
tire easily) in patients who already suffer from this condition.

How to store Clarithromycin
Keep this medicine out of the sight and reach of children.
Do not store above 25°C.

How to report side effects
If you get any side effects, talk to your doctor, pharmacist
or nurse. This includes all possible side effects not listed in
this leaflet. You can also report side effects directly via HPRA
website: HPRAonline. If you think a child may have
swallowed any, contact your local hospital casualty department or tell your
doctor for advice.

If you are unsure which tablets you should be taking, or for
further information, please consult your physician or pharmacist.

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