PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Pharma-Q Clindamycin Injection 600 mg/4 ml solution for injection

Read all of this leaflet carefully before you are given Pharma-Q Clindamycin Injection 600 mg/4 ml

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Pharma-Q Clindamycin Injection 600 mg/4 ml** 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.

1. WHAT PHARMA-Q CLINDAMYCIN INJECTION 600 mg/4 ml CONTAINS

The active ingredient is clindamycin phosphate.

Each 4 ml injection contains 600 mg clindamycin as the phosphate and 0,9 % v/v benzyl alcohol as local anaesthetic.

The other ingredients are disodium edetate, nitrogen, sodium hydroxide, water for injection.

2. WHAT PHARMA-Q CLINDAMYCIN INJECTION 600 mg/4 ml IS USED FOR

Pharma-Q Clindamycin Injection 600 mg/4 ml belongs to a group of medicines known as antibiotics. These medicines fight infection in the body.

Pharma-Q Clindamycin Injection 600 mg/4 ml is used primarily to treat:

- Anaerobic infections caused by anaerobic bacteria (bacteria which cannot grow in the presence of oxygen), including respiratory tract infections, skin and soft tissue infections and peritonitis (inflammation of the membrane which lines the abdominal cavity)
- It may be used to treat susceptible aerobic bacteria (bacteria which grow in the presence of oxygen)
- It may be used to treat patients who are allergic to penicillins
- It is also used to treat bone and joint infections but it is unlikely to be effective against central nervous system infections (e.g. meningitis) because of its poor penetration of the blood brain barrier.

Your doctor will prescribe **Pharma-Q Clindamycin Injection 600 mg/4 ml** for you**,** if you suffer from any of the above conditions and if alternative, less toxic agents are unsuitable.

3. BEFORE YOU ARE GIVEN PHARMA-Q CLINDAMYCIN 600 mg/4 ml

You should NOT be given Pharma-Q Clindamycin Injection 600 mg/4 ml

- If you are allergic to clindamycin phosphate or lincomycin or to any ingredients in this medicine (see **WHAT PHARMA-Q CLINDAMYCIN INJECTION 600 mg/4 ml CONTAINS**)
- If you suffer from gastro-intestinal disease, particularly if you have a history of colitis (inflammation of the colon)
- If you suffer from meningitis since no significant levels are attained in the cerebrospinal fluid, even in the presence of inflamed meninges
- If you are pregnant or breastfeeding since safety for use in pregnancy and lactation has not been established (see **Pregnancy and Breastfeeding**).

Take special care with Pharma-Q Clindamycin Injection 600 mg/4 ml

Pharma-Q Clindamycin Injection 600 mg/4 ml

- Will be used with caution if you are using other muscle relaxants since it also displays muscle relaxing activity
- Will be used with caution if you suffer from liver and kidney problems. Periodic blood tests or liver function tests will be carried out if you are receiving prolonged therapy
- If it has to be used in your infant who is less than 1 month in age, appropriate monitoring of organ system functions will be carried out
- Will be reserved for serious infections where less toxic antimicrobial agents are unsuitable since therapy with this injection has been associated with severe inflammation of the colon, which may end fatally
- Will be used with caution if you are an atopic patient (hyperallergic-you present with eczema, allergic rhinitis, allergic asthma and allergic conjunctivitis etc).

Pharma-Q Clindamycin Injection 600 mg/4 ml associated colitis

- The inflammation of the colon is usually characterized by severe persistent diarrhoea and severe abdominal cramps and may be associated with the passage of blood and mucus
- When significant diarrhoea occurs, the medication will be discontinued
- Diarrhoea, inflammation of the colon and pseudomembranous colitis (infection of the colon) may occur for up to several weeks after therapy

If you are old or if you are a female patient, you are more likely to experience severe diarrhoea or pseudomembranous colitis (infection of the colon).

Pregnancy and Breastfeeding

You should not be given **Pharma-Q Clindamycin Injection 600 mg/4 ml** during pregnancy and lactation since the safety and efficacy of this injection has not been established (see **You should NOT be given Pharma-Q Clindamycin Injection 600 mg/4 ml**).

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before you receive **Pharma-Q Clindamycin Injection 600 mg/4 ml.**

Driving and using machinery

You should avoid potentially hazardous tasks such as driving and operating machinery until you know how **Pharma-Q Clindamycin Injection 600 mg/4 ml** affects you.

Taking other medicines with Pharma-Q Clindamycin Injection 600 mg/4 ml

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

Pharma-Q Clindamycin Injection 600 mg/4 ml

Activity with other antibiotics

1. Synergistic effects occur when used in combination with antibiotics like:
   - Ceftazidime
   - Metronidazole
   - Ciprofloxacin
   - Aminoglycosides (for certain infections only)
   - Pyrimethamine and folinic acid (for treatment of encephalitis [inflammation of the brain] in patients with AIDS)
   - Primaquine (for the treatment of mild to moderate pneumonia in patients with AIDS).

2. It may decrease the activity of ampicillin (penicillin antibiotic).

Pharma-Q Clindamycin Injection 600 mg/4 ml

Activity with other anti-diarrhoeal agents

- Concomitant use with diphenoxylate or loperamide (over the counter anti-diarrhoeals) or opioids (pain killers), may increase the syndrome of antibiotic associated inflammation of the colon
- When given together with a kaolin-pectin suspension, the suspension reduces the absorption rate.

4. HOW TO RECEIVE PHARMA-Q CLINDAMYCIN INJECTION 600 mg/4 ml

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

Always receive **Pharma-Q Clindamycin Injection 600 mg/4 ml** exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

Pharma-Q Clindamycin Injection 600 mg/4 ml will be given to you by a doctor or nurse in hospital. Your doctor will choose the dose that is right for you.

Pharma-Q Clindamycin Injection 600 mg/4 ml

- May be injected into your muscle or given to you by direct injection into the vein
- Different dosages will be calculated for adults and children over the age of one month
- These dosages will be worked out according to how severe the infection is
- Dosages and safety in infants less than one month old has not been established.

If you have the impression that the effect of **Pharma-Q Clindamycin Injection 600 mg/4 ml** is too strong or too weak, talk to your doctor or pharmacist.

If you are given more Pharma-Q Clindamycin Injection 600 mg/4 ml than you should

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the injection.

Pharma-Q Clindamycin Injection 600 mg/4 ml overdose

- For symptoms of overdose see **POSSIBLE SIDE EFFECTS** and **Special care should be taken with Pharma-Q Clindamycin Injection 600 mg/4 ml**
- Your treatment will be symptomatic and supportive.

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

If you missed a dose of Pharma-Q Clindamycin Injection 600 mg/4 ml

If you think that you did not receive a dose of **Pharma-Q Clindamycin Injection 600 mg/4 ml**, contact your doctor.

If you have any further questions on the use of **Pharma-Q Clindamycin Injection 600 mg/4 ml**, ask your doctor, nurse, or pharmacist.

5. POSSIBLE SIDE EFFECTS

Pharma-Q Clindamycin Injection 600 mg/4 ml can have side effects.

Not all side effects reported for **Pharma-Q Clindamycin Injection 600 mg/4 ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **Pharma-Q Clindamycin Injection 600 mg/4 ml**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following serious side effects occur, stop receiving Pharma-Q Clindamycin Injection 600 mg/4 ml and tell your doctor immediately or go to the casualty department at your nearest hospital

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, rash or itching.

These serious side effects and you may have had an allergic reaction to **Pharma-Q Clindamycin Injection 600 mg/4 ml.** You may need urgent medical care or hospitalisation.

Tell your doctor immediately if you notice any of the following

- Abnormalities of liver function tests and jaundice (too much bile in the blood causing yellow skin, gums etc).
- Decreased red and white blood cells and platelets
- Sudden, life-threatening severe allergic reaction due to injection in the vein, thrombophlebitis (inflammation of the vein with clot formation) after injection in the vein.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following

- Diarrhoea, which can be severe and persistent
- Nausea, vomiting, abdominal cramps and abnormality of taste.
- Skin rashes and hives.

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

6. STORING AND DISPOSING OF PHARMA-Q CLINDAMYCIN INJECTION 600 mg/4 ml

Keep ampoule in container until required for administration.

Store at or below 25 °C.

Protect from light

KEEP ALL MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF PHARMA-Q CLINDAMYCIN INJECTION 600 mg/4 ml

10 x 5 ml clear, colourless glass, type 1 ampoule, containing 4 ml.

8. IDENTIFICATION OF PHARMA-Q CLINDAMYCIN INJECTION 600 mg/4 ml

A clear, colourless to faint yellow solution in a 5 ml ampoule, containing 4 ml.

9. REGISTRATION NUMBER

32/20.1.1/0502

10. NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

11. THIS LEAFLET WAS LAST REVISED IN

06 March 2015

6 March 2015

12. ACCESS TO THE CORRESPONDING PROFESIONAL INFORMATION

To follow