

Approved Patient Information Leaflet for Clindamycin 600 mg/4 ml Fresenius

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CLINDAMYCIN 600 mg/4 ml FRESENIUS solution for injection

Clindamycin phosphate

Sugar free

Read all of this leaflet carefully before you are given CLINDAMYCIN 600 mg/4 ml FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What CLINDAMYCIN 600 mg/4 ml FRESENIUS is and what it is used for
2. What you need to know before you are given CLINDAMYCIN 600 mg/4 ml FRESENIUS
3. How CLINDAMYCIN 600 mg/4 ml FRESENIUS will be given
4. Possible side effects
5. How to store CLINDAMYCIN 600 mg/4 ml FRESENIUS

6. Contents of the pack and other information.

1. What CLINDAMYCIN 600 mg/4 ml FRESENIUS is and what it is used for

CLINDAMYCIN 600 mg/4 ml FRESENIUS contains a medicine called clindamycin phosphate, which is an antibiotic used in the treatment of serious bacterial infections.

2. What you need to know before CLINDAMYCIN 600 mg/4 ml FRESENIUS is given to you

CLINDAMYCIN 600 mg/4 ml FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to clindamycin, lincomycin, doxorubicin or any of the other ingredients of CLINDAMYCIN 600 mg/4 ml FRESENIUS (listed in section 6)
- if you currently have a problem with diarrhoea or have a history of problems with your stomach or intestines
- if you have meningitis (inflamed brain membranes)
- in premature babies or neonates.

Warnings and precautions:

Tell your doctor or health care provider before given the injection:

- If you have liver problems.
- Acute kidney disorders may occur. Please inform your doctor about any medication you currently take and if you have any existing problems with your kidneys. If you experience decreased urine output, fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea you should contact your doctor immediately.
- If you have allergic conditions including asthma, eczema or hay fever.
- If you have porphyria (a rare hereditary disease in which there is abnormal metabolism of the

blood pigment haemoglobin).

- If you have ever had problems with your stomach or bowels.

You should also know that:

- The benzyl alcohol may cause fatal “gaspings syndrome” in neonates.
- CLINDAMYCIN 600 mg/4 ml FRESENIUS has been associated with colitis (a severe form of diarrhoea with pain). If you develop severe, prolonged or bloody diarrhoea during or after using CLINDAMYCIN 600 mg/4 ml FRESENIUS, tell your doctor immediately since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur even after 2 to 3 weeks following treatment with antibiotics, such as CLINDAMYCIN 600 mg/4 ml FRESENIUS.
- The prolonged use of CLINDAMYCIN 600 mg/4 ml FRESENIUS may cause superinfections, particularly yeast infections.
- CLINDAMYCIN 600 mg/4 ml FRESENIUS can increase the effect of muscle relaxants causing difficulty to breathe.
- CLINDAMYCIN 600 mg/4 ml FRESENIUS can reduce the effectiveness of combined oral contraceptives. Additional contraceptive methods should be used during treatment and for up to seven days after treatment has been stopped.

Other medicines and CLINDAMYCIN 600 mg/4 ml FRESENIUS:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor if you are taking any of the following medicines:

- CLINDAMYCIN 600 mg/4 ml FRESENIUS may increase the effect of muscle relaxants and

cause breathing difficulties. If you are in hospital and going to have an operation or using medicine to help your muscles relax, please inform your health care provider.

CLINDAMYCIN 600 mg/4 ml FRESENIUS may counteract the effects of medicines called parasympathomimetics. Parasympathomimetics include:

- Pilocarpine and physostigmine (used to treat glaucoma).
- Neostigmine and pyridostigmine (used to treat myasthenia gravis, a condition in which the muscles become weak and tire easily).
- Bethanechol (used to treat obstruction of the bowel and to relieve difficulties in urinating after an operation).
- Carbachol (used to relieve fluid pressure inside the eye and to constrict your pupils during surgery).
- Edrophonium (used to diagnose a muscle disorder called myasthenia gravis).
- Donepezil, rivastigmine, galantamine (used to treat Alzheimer's disease).

CLINDAMYCIN 600 mg/4 ml FRESENIUS should not be used with erythromycin (used to treat bacterial infections).

The simultaneous use of CLINDAMYCIN 600 mg/4 ml FRESENIUS and vitamin K antagonists (e.g. warfarin, acenocoumarol and fluindione) may cause you to bleed more. Your doctor may need to perform regular blood tests to check how well your blood can clot.

If you are taking rifampicin, a medicine used to treat tuberculosis and other bacterial infections, the effectiveness of CLINDAMYCIN 600 mg/4 ml FRESENIUS may be reduced.

CLINDAMYCIN 600 mg/4 ml FRESENIUS with food and drink

It is unlikely that food and beverages will make CLINDAMYCIN 600 mg/4 ml FRESENIUS less effective if taken at the same time.

Pregnancy and breastfeeding

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 receiving CLINDAMYCIN 600 mg/4 ml FRESENIUS.

CLINDAMYCIN 600 mg/4 ml FRESENIUS appears in breast milk. In the breastfed infant, diarrhoea, fungal infections and hypersensitivity (allergic reaction) can occur.

CLINDAMYCIN 600 mg/4 ml FRESENIUS contains benzyl alcohol (0,036 ml/4 ml as preservative) and must not be given to premature babies or babies less than one month old. It may cause allergic and toxic reactions and has caused serious side effects in the brain, heart, blood and breathing rate in children, which have been fatal in some cases.

CLINDAMYCIN 600 mg/4 ml FRESENIUS contains sodium

Tell your doctor if you are on a salt-restricted diet. CLINDAMYCIN 600 mg/4 ml FRESENIUS contains less than 1 mmol sodium (23 mg) per 4 ml, that is to say essentially sodium free.

Driving and using machines

It is not always possible to predict to what extent CLINDAMYCIN 600 mg/4 ml FRESENIUS may interfere with your daily activities. You should ensure that you do not engage in the above activities

until you are aware of the measure to which CLINDAMYCIN 600 mg/4 ml FRESENIUS affects you.

No special effects have been reported with CLINDAMYCIN 600 mg/4 ml FRESENIUS that may impair your ability to drive a vehicle or operate machines. You should however not drive a vehicle or operate machines if you do not feel well.

3. How CLINDAMYCIN 600 mg/4 ml FRESENIUS will be given

You will not be expected to give yourself CLINDAMYCIN 600 mg/4 ml FRESENIUS. It will be given to you by a person who is qualified to do so.

CLINDAMYCIN 600 mg/4 ml FRESENIUS will be given to you as an injection into your muscle (intramuscular) or into your vein (intravenous). Your doctor will decide on a suitable dose for you, depending on the severity of the infection. Your doctor will tell you how long your treatment with CLINDAMYCIN 600 mg/4 ml FRESENIUS will last.

If you have the impression that the effect of CLINDAMYCIN 600 mg/4 ml FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more CLINDAMYCIN 600 mg/4 ml FRESENIUS than you should

Since a health care provider will administer CLINDAMYCIN 600 mg/4 ml FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the symptoms of the overdosage.

If you missed a dose of CLINDAMYCIN 600 mg/4 ml FRESENIUS

Since a health care provider will administer CLINDAMYCIN 600 mg/4 ml FRESENIUS, it is unlikely that a dose will be missed.

4. Possible side effects

CLINDAMYCIN 600 mg/4 ml FRESENIUS can have side effects.

Not all side effects reported for CLINDAMYCIN 600 mg/4 ml FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while you are receiving CLINDAMYCIN 600 mg/4 ml FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving CLINDAMYCIN 600 mg/4 ml FRESENIUS and tell your doctor immediately:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash, fever, hives, peeling skin or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CLINDAMYCIN 600 mg/4 ml FRESENIUS. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- Diarrhoea with blood and mucus, severe stomach cramps, nausea (feeling sick), vomiting (being sick). These side effects may occur frequently, during or after treatment, and may be a sign of bowel inflammation.
- Yellowing of your skin and eyes (jaundice or liver disorders).
- Fatal “gasping syndrome” in neonates (serious breathing disorder).

- Blood disorders. A low white blood cell count may be suspected if you get infections easily. A deficiency of platelets in the blood may be suspected if you bruise easily and have slow blood clotting after an injury.
- Heart and lung stop functioning (when the heart suddenly stops pumping blood around the body).
- Potentially life-threatening skin rashes
 - Blistering and peeling of large areas of your skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips.
 - A widespread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30 % of the body surface – toxic epidermal necrolysis).
 - Widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis).
 - Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge), known as erythema multiforme.
 - Fever, swollen lymph nodes or skin rash. These may be symptoms of a condition known as DRESS (drug reaction with eosinophilia and systemic symptoms) which can be severe and life-threatening. The symptoms of DRESS usually begin several weeks after CLINDAMYCIN 600 mg/4 ml FRESINIUS has been administered.
 - A rare skin eruption characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (acute generalised exanthematous pustulosis – AGEP).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pain, swelling, redness and tenderness in vein or pain and swelling in leg.

- Abnormalities in liver function tests.
- Rash, characterised by a flat red area on the skin with small bumps.

Less frequent side effects:

- Change in sense of taste, unpleasant or metallic taste.
- Low blood pressure (feeling light-headed, dizzy or faint).
- Nausea (feeling sick).
- Urinating less than usual, kidney problems.
- Uraemia. Some signs may be progressive weakness and easy fatigue, nausea and vomiting, muscle atrophy, tremors, abnormal mental function, frequent shallow respiration.
- Pain and abscess (boil) at the site of injection, inflammation at the injection site.

Frequency not known:

- Vaginal thrush, sore and itchy vagina and/or discharge.
- Vomiting (being sick).
- Inflammation of lining of the oesophagus (food pipe), open sores or lesions in the lining of the oesophagus.
- Acute kidney failure.

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, pharmacist or nurse. You can also report side effects 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 CLINDAMYCIN 600 mg/4 ml FRESENIUS.

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store CLINDAMYCIN 600 mg/4 ml FRESENIUS

CLINDAMYCIN 600 mg/4 ml FRESENIUS will be stored in the pharmacy or in the hospital wards.

Store at or below 25 °C.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What CLINDAMYCIN 600 mg/4 ml FRESENIUS contains

The active ingredient is clindamycin.

Each 4 ml CLINDAMYCIN 600 mg/4 ml FRESENIUS contains 600 mg clindamycin (as clindamycin phosphate).

The other ingredients are disodium edetate, water for injection, sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment) and 0,9 % v/v benzyl alcohol (as preservative).

What CLINDAMYCIN 600 mg/4 ml FRESENIUS looks like and contents of the pack

A clear colourless to faint yellow solution.

5 ml clear type I glass ampoule.

Pack size: Ten ampoules per carton.

Holder of the Certificate of Registration and Manufacturer

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This leaflet was last revised in

16 May 2022

Registration number

Y/20.1.1/254