CLINDAMYCIN VIATRIS

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about receiving CLINDAMYCIN VIATRIS, speak to your doctor or pharmacist.

1. Why am I being given CLINDAMYCIN VIATRIS?

CLINDAMYCIN VIATRIS contains the active ingredient clindamycin phosphate. CLINDAMYCIN VIATRIS treats infections in different parts of the body caused by bacteria. For more information, see Section 1. Why am I being given CLINDAMYCIN VIATRIS? in the full CMI.

2. What should I know before I am given CLINDAMYCIN VIATRIS?

Do not receive CLINDAMYCIN VIATRIS if you have ever had an allergic reaction to clindamycin or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have liver, kidney, bowel, stomach or gut problems, or have had severe diarrhoea associated with the use of antibiotics, or history of allergy to different things or any other medical conditions, take any other medicines, are pregnant or breastfeeding or plan to become pregnant or breastfeed.** For more information, see Section 2. What should I know before I am given CLINDAMYCIN VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CLINDAMYCIN VIATRIS and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How am I given CLINDAMYCIN VIATRIS?

Your dose and how it should be given to you will be determined by your doctor. Usually CLINDAMYCIN VIATRIS will be given to you intramuscularly (into a muscle) or intravenously (into the vein by drip) in a hospital by a healthcare professional. More instructions can be found in Section 4. How am I given CLINDAMYCIN VIATRIS? in the full CMI.

5. What should I know while being given CLINDAMYCIN VIATRIS?

Things you should do	• Tell your doctor, dentist or pharmacist you visit that you are being given CLINDAMYCIN VIATRIS. • If you get severe diarrhoea, severe stomach pain; a severe skin rash; chest pain, shortness of breath, nausea, vomiting, sweating, fast/irregular heartbeats; or feel lightheaded or dizzy tell your doctor, pharmacist, or nurse immediately. Do this even if it occurs several weeks after you have been given CLINDAMYCIN VIATRIS injection.
Things you should not do	• Do not stop receiving CLINDAMYCIN VIATRIS injection because you are feeling better, unless advised by your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how CLINDAMYCIN VIATRIS affects you.
Drinking alcohol	• No information available.

For more information, see Section 5. What should I know while being given CLINDAMYCIN VIATRIS? in the full CMI.

6. Are there any side effects?

Side effects may include discomfort at injection site; pain/stiffness/swelling in joints; skin rash; stomach ache; vomiting; nausea; change/loss of taste; vaginal infection; red rash on folds of the buttocks, groin, armpit or behind the knee.

Serious side effects may include low blood pressure; severe diarrhoea which may have blood and mucus; weight loss and fevers, night sweats, fatigue, cough, pain, weakness, confusion; severe chills and sore throat or mouth ulcers; bleeding/bruising more easily than normal; signs of allergy on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing; little or no urine; yellowing of the eyes or skin; severe swelling and redness along a vein; chest and heart discomfort, fast/pounding/irregular heartbeat.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CLINDAMYCIN VIATRIS

Active ingredient(s): *clindamycin phosphate*

Consumer Medicine Information (CMI)

This leaflet provides important information about how CLINDAMYCIN VIATRIS is given. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about receiving CLINDAMYCIN VIATRIS.**

Where to find information in this leaflet:

1. Why am I being given CLINDAMYCIN VIATRIS?
2. What should I know before I am given CLINDAMYCIN VIATRIS?
3. What if I am taking other medicines?
4. How CLINDAMYCIN VIATRIS is given
5. What should I know while being given CLINDAMYCIN VIATRIS?
6. Are there any side effects?
7. Product details

1. Why am I being given CLINDAMYCIN VIATRIS?

CLINDAMYCIN VIATRIS contains the active ingredient clindamycin phosphate. Clindamycin is an antibiotic. Clindamycin works by killing or stopping the growth of bacteria causing your infection.

CLINDAMYCIN VIATRIS is used to treat infections in different parts of the body caused by bacteria.

Clindamycin will not work against viral infections such as colds or flu.

CLINDAMYCIN VIATRIS is recommended for patients who are allergic to penicillin or patients for whom, in the judgment of the doctor, penicillin is inappropriate.

Your doctor may have prescribed CLINDAMYCIN VIATRIS for another reason.

Ask your doctor if you have any questions about why CLINDAMYCIN VIATRIS has been prescribed for you.

2. What should I know before I am given CLINDAMYCIN VIATRIS?

Warnings

Do not take CLINDAMYCIN VIATRIS if:

- you are allergic to:
  - clindamycin or lincomycin
  - any of the other ingredients listed at the end of this leaflet

  Symptoms of an allergic reaction may include:
- shortness of breath
- wheezing and difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Always check the ingredients to make sure you can receive CLINDAMYCIN VIATRIS.

You should not be given CLINDAMYCIN VIATRIS after the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any medicines, foods, preservatives or dyes.
- have or have any of the following medical conditions
  - severe diarrhoea associated with the use of antibiotics
  - have liver disease
  - have kidney disease
  - have a history of bowel disease or any gastrointestinal (stomach or gut) problems
- take any medicines for any other condition

If you have not told your doctor or pharmacist about any of the above, do so before you are given CLINDAMYCIN VIATRIS.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with CLINDAMYCIN VIATRIS and affect how it works. These include:

- erythromycin, ciprofloxacin, clarithromycin, rifampicin, rifaximin - used to treat bacterial infections
- fluconazole, itraconazole, ketoconazole, voriconazole - used to treat fungal infections
- carbamazepine, phenobarbital, phenytoin, primidone - used to manage seizures
- imatinib, enzalutamide, apalutamide, midostaurin - used to treat certain cancers

- aprepitant - used to treat nausea and vomiting associated with cancer treatment
- lumacaftor - used for the treatment of cystic fibrosis
- St. John's wort (hypericum perforatum) - used to assist emotional health
- dexamethasone - used to treat various inflammatory, endocrine or rheumatic conditions
- diltiazem, verapamil - used to treat angina or high blood pressure
- ritonavir - used to treat HIV/AIDS
- medicines used for muscle relaxation in anaesthesia and some medicines that may be used during surgery in an intensive care setting.

These medicines may be affected by clindamycin or may affect how well it works. You may need different amounts of CLINDAMYCIN VIATRIS or you may need to take different medicines.

- Your doctor or pharmacist may have more information on medicines to be careful with or avoid while I am given CLINDAMYCIN VIATRIS.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CLINDAMYCIN VIATRIS.

4. How CLINDAMYCIN VIATRIS is given

How much CLINDAMYCIN VIATRIS is given

Your dose and how it should be given to you will be determined by your doctor. This depends on your condition, the infection being treated and how severe it is.

For children, the doctor will work out the dose based on their age, body weight and how severe the infection is.

It is important that you complete the full course prescribed by your doctor so that all of the bacteria causing your infection will be killed. If the course is not completed, these bacteria may continue to grow and multiply so that your infection may not clear completely or may return.

How CLINDAMYCIN VIATRIS is given

Usually CLINDAMYCIN VIATRIS will be given to you intramuscularly (into a muscle) or intravenously (into the vein by drip) in a hospital by a healthcare professional.

If given intravenously, CLINDAMYCIN VIATRIS will be mixed with the appropriate amount of diluent before use. This will be prepared by your pharmacist or health care professional.

If you are given too much CLINDAMYCIN VIATRIS

As CLINDAMYCIN VIATRIS is usually given to you in hospital under the close supervision of your doctor, it is unlikely that you will receive too much.

However, if you experience severe side effects after being given CLINDAMYCIN VIATRIS, tell your doctor or nurse immediately, or if you are not already in hospital go to Accident and Emergency at the nearest hospital or immediately contact the Poisons Information Centre for advice on overdose (Call 13 11 26).

Symptoms of an overdose are the same as those listed under below 6. Are there any side effects but are usually of a more severe nature.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep the telephone numbers for these services handy. Have the CLINDAMYCIN VIATRIS box or this leaflet available to give details if needed.

5. What should I know while being given CLINDAMYCIN VIATRIS?

Things you must do

- **If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.**
- **If you develop severe stomach pain or severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after the CLINDAMYCIN VIATRIS has been stopped**.

  Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.
- **If you get a severe skin rash tell your doctor immediately. Do this even if the rash occurs after CLINDAMYCIN VIATRIS has been stopped.**

  A severe skin rash may mean you are having an allergic reaction to CLINDAMYCIN VIATRIS. You may need urgent medical care.
- **If you have chest pain, shortness of breath, nausea and vomiting, sweating and fast or irregular heartbeats, tell your doctor or nurse immediately.**

  This may mean you are having an allergic reaction to CLINDAMYCIN VIATRIS.
- **If you feel lightheaded or dizzy, tell your doctor or nurse immediately.**
- **If you get a sore, white mouth or tongue while being given this medicine or soon after CLINDAMYCIN VIATRIS has been stopped, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.**

  This may mean you have a fungal/ yeast infection called thrush.

  Sometimes the use of clindamycin allows fungi/yeast to grow and the above symptoms to occur.

  Clindamycin does not work against fungi/yeast.
- **If you become pregnant while you are being given CLINDAMYCIN VIATRIS, tell your doctor immediately.**
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you received CLINDAMYCIN VIATRIS.
- Tell all doctors, dentists and pharmacists who are treating you that you received CLINDAMYCIN VIATRIS.
- **Tell your doctor if you are about to have any blood tests.** CLINDAMYCIN VIATRIS may interfere with the results of some tests.

- **Keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- **Do not stop receiving CLINDAMYCIN VIATRIS because you are feeling better, unless advised by your doctor.**
- **Do not take any medicines for diarrhoea without first checking with your doctor.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CLINDAMYCIN VIATRIS affects you.

Drinking alcohol

No information available

Looking after your medicine

CLINDAMYCIN VIATRIS will normally be stored in a hospital ward or pharmacy protected from light, in a cool dry place where the temperature stays below 25°C.

When to discard your medicine

CLINDAMYCIN VIATRIS will be opened for use on you. It will be used only once and then it will be discarded. It will never be stored after it is opened nor used for more than one person.

Getting rid of any unwanted medicine

Any unwanted medicine will be disposed of in safe manner by doctor, nurse or pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

It can be difficult to tell whether side effects are the result of being given CLINDAMYCIN VIATRIS, effects of your condition or side effects of other medicines you may be taking. For this reason, it is important to tell your doctor of any changes in your condition.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
• stomach pain, cramps or discomfort • nausea and/or vomiting • diarrhoea • skin rash which may be red or itchy, irritation of the skin	**Speak to your doctor if you have any of these less serious side effects.**
• red rash on the folds of the buttocks, groin, armpit or behind the knee • vaginal infection (thrush) - sore, burning and itchy vagina and/or a thick, white discharge • low blood pressure (feeling of dizziness or light-headedness) • pain, stiffness or swelling in your joints • pain, swelling, itching, redness, warmth, tenderness, lump under the skin or formation of an abscess at the site of the injection • change or loss of taste	

Serious side effects

Serious side effects	What to do
• low blood pressure (dizziness, lightheadedness) • marks on the skin that do not fade when pressed • sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing • moderate or severe skin rash or blisters often with flu-like symptoms • enlarged lymph glands and/or fever • diarrhoea which may have blood and mucus, stomach pain, fever • weight loss and fevers, night sweats, fatigue, cough, chest pain, swelling, stomach pain, rash, pain, weakness, confusion • frequent infections presenting as fever, severe chills, sore throat or mouth ulcers • bleeding or bruising more easily than normal • painful red area of the skin with blistering or peeling, or bleeding in the lips, eyes, mouth, nose and genitals • high fever quickly followed by a skin rash • little or no urine, with drowsiness, nausea, vomiting, breathlessness • yellowing of the eyes or skin, also called jaundice	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• pain, swelling, redness and tenderness in vein, which is extremely tender when touched • swelling in legs, ankles or feet, irregular heartbeat, shortness of breath, • chest pain, fainting	

Rare instances following too rapid intravenous administration

Serious side effects	What to do
• chest discomfort, shortness of breath, weakness, fast-beating, fluttering or pounding heart	**Tell your doctor or nurse straight away.**

After finishing it

Tell your doctor immediately if you notice any of the following side effects while you are being given CLINDAMYCIN VIATRIS or several weeks after treatment has stopped:

- severe stomach cramps;
- watery and severe diarrhoea which may also be bloody; fever, in combination with one or both of the above.

CLINDAMYCIN VIATRIS can cause some bacteria, which are normally present in the bowel and normally harmless to multiply and therefore cause the above symptoms. These are rare, but serious side effects. You may need urgent medical attention.

Do not take any medicine for diarrhoea without first checking with your doctor.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects (for example, abnormal blood test results and certain kidney and liver conditions) can only be found when your doctor does tests from time to time to check on your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CLINDAMYCIN VIATRIS contains

Active ingredient (main ingredient)	clindamycin phosphate
Other ingredients (inactive ingredients)	disodium edetate hydrochloric acid sodium hydroxide water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What CLINDAMYCIN VIATRIS looks like

CLINDAMYCIN VIATRIS appears as a clear, colourless to pale yellow solution free from visible particles.

CLINDAMYCIN VIATRIS 300 mg/2 mL (AUST R 189176)

CLINDAMYCIN VIATRIS 600 mg/4 mL (AUST R 191745)

CLINDAMYCIN VIATRIS is available in a pack of 2 mL or 4 mL glass vial with a rubber stopper and aluminium flip off seal.

Who distributes CLINDAMYCIN VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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