#### **CLINDAMYK**

#### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

## 1. Why am I using CLINDAMYK?

CLINDAMYK contains the active ingredient clindamycin hydrochloride. CLINDAMYK is used to treat infections in different parts of the body caused by bacteria. It works by killing or stopping the growth of the bacteria causing your infection.

For more information, see Section <u>1. Why am I using</u> CLINDAMYK? in the full CMI.

# 2. What should I know before I use CLINDAMYK?

Do not use 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 any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know before I use CLINDAMYK?</u> in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with CLINDAMYK 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 do I use CLINDAMYK?

- Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.
- One capsule (150mg) every six hours is the usual dose. The number of capsules may increase with more serious infections.

More instructions can be found in Section <u>4. How do I use CLINDAMYK?</u> in the full CMI.

# 5. What should I know while using CLINDAMYK?

| Things you should do      | <ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using CLINDAMYK.</li> <li>If you get severe diarrhea, tell your doctor, pharmacist or nurse immediately.</li> </ul>                 |
|---------------------------|--|
| Things you should not do  | <ul> <li>Do not take this medicine to treat any other complaints unless your doctor tells you to.</li> <li>Do not give your medicine to anyone else, even if they have the same condition as you.</li> </ul> |
| Driving or using machines | <ul> <li>Be careful before you drive or use any machines or tools until you know how CLINDAMYK affects you</li> </ul>  |
| Drinking alcohol          | <ul> <li>Tell your doctor if you<br/>drink alcohol.</li> </ul>   |

# Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it.
- Keep your medicine in a cool dry place where the temperature will stay below 25°C.

For more information, see Section <u>5. What should I know while using CLINDAMYK?</u> in the full CMI.

## 6. Are there any side effects?

The common side effects include oral thrush - white, furry, sore tongue and mouth, vaginal thrush - sore and itchy vagina and/or discharge, stomach cramping, stomach discomfort, diarrhoea, heart burn, loss of appetite, skin rash, joint pain and swelling.

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

#### **CLINDAMYK**

Active ingredient(s): clindamycin hydrochloride

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using CLINDAMYK. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CLINDAMYK.

#### Where to find information in this leaflet:

- 1. Why am I using CLINDAMYK?
- 2. What should I know before I use CLINDAMYK?
- 3. What if I am taking other medicines?
- 4. How do I use CLINDAMYK?
- 5. What should I know while using CLINDAMYK?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using CLINDAMYK?

CLINDAMYK contains the active ingredient clindamycin hydrochloride. CLINDAMYK is an antibiotic.

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

It works by killing or stopping the growth of the bacteria causing your infection.

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

Clindamycin is recommended for patients who are allergic to penicillin or patients for whom penicillin is not suitable.

# Ask your doctor if you have any questions about why Clindamycin has been prescribed for you.

Your doctor may have prescribed Clindamycin for another reason.

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

Clindamycin capsules are not recommended in children for formulation reasons.

Clindamycin is not addictive.

# 2. What should I know before I use CLINDAMYK?

#### **Warnings**

#### Do not use CLINDAMYK if:

- you are allergic to clindamycin hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- Any medicine containing lincomycin.
- lactose or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.
- Rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

#### Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition.

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 <u>6</u>. Are there any side effects?

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Clindamycin crosses the placenta and therefore should only be used in pregnancy if clearly needed.

# Clindamycin capsules are not recommended during breast feeding.

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

If your have not told your doctor about any of the above, tell them before you start taking this medicine.

# 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 interact with clindamycin. These include:

- Erythromycin, used to treat bacterial infections.
- Rifampicin, used to treat bacterial infections.
- Medicines used for muscle relaxation in anesthesia.

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

Other medicines not listed above may also interact with clindamycin.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

### 4. How do I use CLINDAMYK?

#### How much to take / use

Follow all directions given to you by your doctor or pharmacist carefully.

They may be different from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

#### **Adults**

One capsule (150mg) every six hours is the usual dose. The number of capsules may increase with more serious infections.

Continue taking clindamycin until you finish the box or until your doctor recommends. Check with your doctor if you are not sure how long you should be taking it.

Do not stop taking clindamycin capsules because you are feeling better.

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

#### When to take CLINDAMYK

Space the doses of this medicine evenly apart throughout the day and take them at about the same time each day.

- CLINDAMYK should be used taken at the same time each day will have the best effect and will also help your remember when to take it.
- It does not matter if you take it before, with or after food.

#### How to take CLINDAMYK

Clindamycin capsules should be swallowed whole, with a full glass of water.

Do not take CLINDAMYK immediately before lying down. You must wait at least half an hour.

#### If you forget to use CLINDAMYK

CLINDAMYK should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicines as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

#### If you use too much CLINDAMYK

If you think that you have used too much CLINDAMYK, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using CLINDAMYK?

#### Things you should do

#### Call your doctor straight away if you:

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

# If you get severe diarrhea, tell your doctor, pharmacist or nurse immediately.

Do this even if it occurs several weeks after you have stopped taking CLINDAMYK.

Diarrhea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

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

If you get a severe skin rash tell your doctor immediately. Do this even if the rash occurs after clindamycin has been stopped.

A severe skin rash may mean you are having an allergic reaction to clindamycin. You may need urgent medical care.

If you get a sore, white mouth or tongue while taking or soon after stopping clindamycin, 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 are going to have surgery, tell the surgeon or anesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you feel that clindamycin is not helping your condition, tell your doctor.

Tell your doctor if, for any reason, you have not used clindamycin exactly as prescribed.

Remind any doctor, dentist or pharmacist you visit that you are using CLINDAMYK.

### Things you should not do

- Do not take this medicine to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

#### **Driving or using machines**

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

Speak to your doctor or pharmacist to know if CLINDAMYK affects your driving.

#### **Drinking alcohol**

Tell your doctor if you drink alcohol.

#### Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it.
- If you take your medicine out of its original packaging it may not keep well.
- Keep your medicine in a cool dry place where the temperature will stay below 25°C.
- Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it one a windowsill or in the car.

Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

# 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.

# Less serious side effects

| Less serious side effects   | What to do  |
|---|---|
| <ul> <li>Oral thrush- white, furry, sore tongue and mouth</li> <li>Vaginal thrush-sore and itchy vagina and/or discharge</li> <li>Stomach cramping</li> <li>Stomach discomfort</li> <li>Inflammation of the food pipe; discomfort and/or pain of the food pipe</li> <li>Loss or distorted sense of taste</li> <li>Nausea and/or vomiting</li> <li>Heartburn</li> <li>Diarrhea</li> <li>Loss of appetite</li> <li>Skin rash; irritation of the skin</li> <li>Jaundice (yellowing of</li> </ul> | Speak to your doctor if you have any of these less serious side effects and they worry you. |
| the skin)  • Joint pain and swelling  |   |

## **Serious side effects**

| Serious side effects  | What to do   |
|---|--|
| <ul> <li>Severe stomach cramps</li> <li>Watery and severe diarrhea which may also be bloody</li> <li>Fever, in combination with both of the above.</li> </ul> | 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. |

# Very serious side effects

| Very serious side effects   | What to do  |
|---|---|
| <ul> <li>Symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, throat or other parts of the body, rash and itching or hives on the skin.</li> <li>Moderate or severe skin rash or blisters often with flu-like symptoms</li> </ul> | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. |

| Very serious side effects   | What to do |
|---|------------|
| <ul> <li>Enlarged lymph glands<br/>and/or fever</li> </ul>                                  |            |
| <ul> <li>diarrhea, usually with<br/>blood and mucus,<br/>stomach pain and fever.</li> </ul> |            |
| <ul> <li>Yellowing of the eyes<br/>or skin, also called<br/>jaundice</li> </ul>             |            |

# 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 tests results and certain kidney and liver conditions can only be found when your doctors does tests from time to time to check on your progress.

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

#### 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 CLINDAMYK contains

| Active ingredient (main ingredient) | Clindamycin (as hydrochloride)                 |
|-------------------------------------|--|
| Other ingredients                   | Lactose monohydrate                            |
| (inactive ingredients)              | Magnesium stearate                             |
|                                     | Maize starch                                   |
|                                     | Purified talc                                  |
|                                     | Titanium dioxide                               |
|                                     | Gelatin  |
|                                     | Black printing ink (shellac, iron oxide black) |
| Potential allergens                 | Contains sugars as lactose.                    |

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

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

#### What CLINDAMYK looks like

CLINDAMYK capsules consist of a white cap and white body imprinted with 'Clin 150' in black printing ink.

**AUST R 214371** 

#### Who distributes CLINDAMYK

#### **SPONSOR**

Arrotex Pharmaceuticals 15-17 Chapel Street Cremorne, VIC 3121

#### **DISTRIBUTOR**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

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