Consumer Medicine Information (CMI) summary

The full CMI 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 ClindaTech?

ClindaTech contains the active ingredient clindamycin hydrochloride. ClindaTech is used on the skin to treat certain forms of acne. For more information, see Section <u>1. Why am I using ClindaTech?</u> in the full CMI.

2. What should I know before I use ClindaTech?

Do not use if you have ever had an allergic reaction to ClindaTech or any of the ingredients listed at the end of the CMI or have a history of inflammatory diseases of the intestines or the large bowel.

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 2. What should I know before I use ClindaTech? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ClindaTech 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 ClindaTech?

Carefully follow all directions given by your doctor or other healthcare professionals.

 Apply no more than twice daily, once in the morning and once at bedtime, to those parts of your skin affected by acne lesions as well as those likely to be affected by acne.

More instructions can be found in Section 4. How do I use ClindaTech? in the full CMI.

5. What should I know while using ClindaTech?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using ClindaTech. If your acne does not improve after a few weeks or becomes worse, see your doctor or pharmacist. The treatment may take up to 8 to 12 weeks before you see a clear improvement with your skin. Talk to your doctor if you are breastfeeding or intend to breastfeed. 	
Things you should not do	 ClindaTech is for external use only. Do not swallow this medicine. Do not apply to open wounds, eyes, around eyelid areas, mouth, lips, mucosa or angles of the nose. 	
Looking after your medicine	 Store below 30°C. Do not freeze or expose to excessive heat and direct light. Keep out of reach of children. 	

For more information, see Section 5. What should I know while using ClindaTech? in the full CMI.

6. Are there any side effects?

Common side effects include dry or peeling skin, skin irritations or rashes, oily skin, reddening of the skin, burning or stinging feeling on the skin and a mild upset stomach.

Serious side effects include stomach problems such as severe pain, cramps, bloody or watery diarrhoea and vomiting and nausea.

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.

Active ingredient: Clindamycin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using ClindaTech. 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 ClindaTech.

Where to find information in this leaflet:

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

1. Why am I using ClindaTech?

ClindaTech contains the active ingredient clindamycin hydrochloride. Clindamycin belongs to a group of medicines called antibiotics.

ClindaTech is used on the skin to treat certain forms of acne. It works by decreasing acne lesions and/or stopping the growth of skin bacteria which cause acne.

It is usually used by itself, but your doctor may prescribe one or more other medicines that are also applied on the skin or taken orally. Your doctor may also prescribe ClindaTech for another purpose. Therefore, ask your doctor if you have any questions why ClindaTech has been prescribed for your condition.

2. What should I know before I use ClindaTech?

Warnings

Do not use ClindaTech if:

- you are allergic to medicines that contain clindamycin (either taken orally or given as an injection) or lincomvcin.
- you are allergic to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have a history of inflammatory diseases of the intestines or the large bowel (colitis, including ulcerative colitis, colitis caused by antibiotics, pseudomembranous colitis, or enteritis).

Check with your doctor if you:

- have a history of stomach or intestinal diseases.
- have any medical conditions especially those affecting the liver or kidney.
- have very sensitive skin or any other skin conditions.
- are taking medication to treat diarrhoea
- take any medicines for any other conditions or are using specific skin products.

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:

Before using ClindaTech, 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. Nursing mothers should not use ClindaTech as it is not known if the active ingredient passes into breast milk, and if there is a possibility that your baby may be affected.

3. What if I am taking other medicines?

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

While using ClindaTech, avoid also using at the same time:

- skin products containing high concentrations of alcohol (e.g. astringents, after-shave lotion, medicated cosmetics) as these will dry your skin and may cause skin irritations.
- other topical acne products or products containing benzoyl peroxide, resorcinol, salicylic acid or tretinoin as concurrent use may cause skin irritations.

Some medicines may interfere with ClindaTech and affect how it works. Avoid using ClindaTech at the same time as other antibiotic medicines, including those which contain clindamycin, erythromycin or tetracycline.

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

4. How do I use ClindaTech?

How to use:

- Your doctor will decide the best treatment according to your skin condition. Follow your doctor's instructions and keep using ClindaTech for the entire course even if your pimples clear up after a few days.
- ClindaTech is for external use only and is applied directly to the skin.
- The usual treatment is to apply a thin film no more than twice daily, once in the morning and once at bedtime.
 Apply to those parts of your skin affected by acne lesions as well as those likely to be affected by acne, not just the pimples themselves.

How to apply ClindaTech:

- 1. Before applying ClindaTech remove any make-up or cosmetics and shave if needed.
- 2. Wash the affected areas thoroughly with warm water and a neutral or pH balanced mild soap, rinse well and pat dry.
- 3. After washing or shaving, allow the skin to dry for 15 to 30 minutes before applying ClindaTech. Since it contains

alcohol, it may irritate your freshly washed or shaved skin.

4. ClindaTech comes in a bottle with an applicator, to apply the medicine directly to the skin.

a. Tilt the bottle and press the tip firmly against your skin. Using a dabbing motion instead of a rolling motion allow the solution to flow through the applicator tip onto the skin.

b. If the flow is too slow, increase the pressure slightly until the solution flows more freely. If the applicator tip becomes dry, turn the bottle upside down and press the tip several times to moisten it

- 5. Apply ClindaTech to the affected areas over the entire face. Avoid applying to open wounds, inflamed skin, eyes or any mucous membranes.
- 6. Be careful applying ClindaTech around the mouth as it has an unpleasant taste.

If you forget to apply ClindaTech:

It is important that you do not miss any doses of ClindaTech. Ask your pharmacist for some guidance if you have trouble remembering when to apply ClindaTech.

ClindaTech should be used regularly at the same time each day. If you miss your application at the usual time, apply ClindaTech as soon as you remember.

If it is almost time for your next application, skip the application you missed and apply your next treatment when you are meant to.

Do not apply a double amount to make up for the application you missed.

If you use too much ClindaTech:

Let your doctor know even if you do have not had any signs of skin discomfort.

5. What should I know while using ClindaTech?

Things you should do:

If your acne does not improve after a few weeks or becomes worse, see your doctor or pharmacist. The treatment may take up to 8 to 12 weeks before you see a clear improvement with your skin.

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

Things you should not do:

- ClindaTech is for external use only. Do not swallow this medicine. If you or someone else accidentally swallow ClindaTech, 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.

- Do not apply to open wounds.
- Do not apply to the eyes, around eyelid areas, mouth, lips, mucosa or angles of the nose.

- If ClindaTech gets in your eyes, immediately wash them out with large amounts of cool, clean water. If your eyes still burn or become painful, contact your doctor immediately.
- Do not apply ClindaTech more often than or longer than what your doctor has prescribed for you because it may cause your skin to become too dry.

Things to be careful of:

- If your skin becomes unnaturally dry or irritated even under normal use, check with your doctor or pharmacist about adjusting the frequency of use or temporarily discontinue application.
- Do not use any skin preparations or medicated dressings on the same affected areas unless your doctor has advised you to do so. If your doctor has prescribed other medicines for applying to the skin, check with your doctor or pharmacist when and how you should apply these medicines.
- Avoid using any peeling agents (e.g. resorcinol, salicylic acid, benzoyl peroxide) or preparations that contain high concentrations of alcohol (astringents, medicated cosmetics).
- Check with your doctor or pharmacist which cosmetics and perfumed toiletries you can use. Use a mild bland soap, or any suitable soap-free cleansers as advised by your pharmacist. It is best not to use cosmetics too heavily or too often because this may make your acne worse. Wash off any cosmetics every time before you apply ClindaTech.

Looking after your medicine:

• Store below 30°C. Do not freeze or expose to excessive heat and direct light.

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.

When to discard your medicine:

Discard the product three months after opening.

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
 Dry or peeling skin Skin irritations or rashes Oily skin Reddening of the skin (erythema) Burning or stinging feeling on the skin at the site of application Mild upset stomach Nausea 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 Stomach problems such as severe pain or cramps Vomiting Bloody or watery diarrhoea (do not take any diarrhoea medication without first checking with your doctor) 	Discontinue using ClindaTech immediately and 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.

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.

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 <u>www.tga.gov.au/</u> <u>reporting-problems</u>. 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 ClindaTech contains:

Active ingredient (main ingredient)	Clindamycin hydrochloride
Other ingredients (inactive ingredients)	Dioctyl malate Ethanol Purified water
Potential allergens	Ethanol

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

What ClindaTech looks like:

ClindaTech is a clear colourless solution packed in a bottle with an outer carton. It is supplied in 50 mL or 100 mL pack sizes.

Australian registration number: AUST R 66687

Who distributes ClindaTech:

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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