

Topcil

Clindamycin hydrochloride

150 mg Capsule

What is in this leaflet

Please read this leaflet carefully before you start taking Topcil.

This leaflet answers some common questions about Topcil. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Topcil against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Topcil is used for

Topcil contains clindamycin, which belongs to a group of medicines called antibiotics. Antibiotics are used to treat infections. Topcil is used to treat bacterial infections in different parts of the body. It works by killing or stopping the growth of the bacteria causing your infection.

Your doctor may have prescribed Topcil for another reason. **Ask your doctor if you have any questions about why Topcil has been prescribed for you.**

Before you take Topcil

When you must not take it

Do not take Topcil if you have an allergy to:

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

Some of the symptoms of an allergic reaction may include:

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

Do not take Topcil if:

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

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

Before you start to take it

Tell your doctor if:

- 1. you have allergies to:**
 - any other medicines.
 - any other substances, such as foods, preservatives or dyes.
- 2. you have, or have had, the following medical conditions:**
 - diarrhoea, especially severe diarrhoea associated with the use of antibiotics.
 - a history of gastrointestinal (stomach or gut) problems, particularly colitis (inflammation of the large bowel).
 - liver or kidney problems.
 - asthma, hay fever or eczema.
 - lactose intolerance.
- 3. you are pregnant or intend to become pregnant.**

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

4. you are breastfeeding planning to breastfeed.

Tell your doctor if you will be breast-feeding while taking Topicil as clindamycin may be passed into breast milk. Your doctor can discuss with you the risks and benefits involved.

5. Topicil is prescribed for an infant less than one month or a child who is unable to swallow capsules.

There is not enough information to recommend the use of this medicine for infants under one month old. In addition, this medicine is used for children who are able to swallow capsules. If your child is unable to swallow capsules, talk to your doctor or pharmacist.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Topicil.

Some medicines may interfere with Topicil. These include:

- muscle relaxants used for operations and hospital procedures.
- erythromycin or rifampicin, an antibiotic used to treat infections.
- oral combined contraceptive pills. You should use extra contraception such as condoms whilst taking Topicil and for seven days after taking Topicil. If in doubt, ask your doctor or pharmacist for advice.

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Topicil.

How to take Topicil

How much to take

Adults

The standard adult dose is one to two capsules (150 mg to 300 mg) every six hours (i.e., 4 times a day). Your doctor may increase this dosage for more serious infections.

Children

For children, your doctor will calculate the correct dose depending on the weight of your child and the type of infection. This medicine is used for children who are able to swallow capsules. If your child is unable to swallow capsules, talk to your doctor or pharmacist.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take. This depends on your condition and the type of infection.

If you take the wrong dose, Topicil Capsules may not work as well and your problem may not improve.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Swallow the capsules with a full glass of water and in an upright position.

When to take it

Take Topicil capsules with or without food (it does not matter), every six hours or as advised by your doctor.

How long to take it

Continue taking your capsules, even if you feel better.

Your condition may return if you stop taking them. Your doctor will tell you when you can stop.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking your capsules as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking Topicil

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Topicil capsules. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

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

If you become pregnant while taking this medicine, tell your doctor immediately.

If you develop severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking Topicil capsules. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicines for diarrhoea without first checking with your doctor.

Your doctor may want to carry out liver and kidney function tests or blood counts during long-term treatment.

If you become pregnant while taking this medicine, tell your doctor immediately.
Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give Topicil to anyone else, even if they have the same condition as you.

Do not stop taking Topicil without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Topicil affects you. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Topicil.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Topicil.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

Common: may affect up to 1 in 10 people

- pain in the stomach/abdomen, diarrhoea.
- abnormal liver function tests (poor liver function).

Uncommon: may affect up to 1 in 100 people

- feeling sick or being sick.
- changes in the way things taste.
- rash characterized by a flat red area on the skin that is covered with small bumps, hives.

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

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is an uncommon side effect which may occur during or after completing treatment with antibiotics and can be a sign of serious bowel inflammation or pseudomembranous colitis.
- blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips.
- yellowing of the skin and whites of the eyes (jaundice).
- infection inside and around the vagina.
- inflammation of the large intestine which causes abdominal pain, fever or diarrhoea due to infection by *Clostridium difficile*
- bruising or bleeding.
- inflammation of the food pipe, or ulcers and/or pain in the food pipe; heartburn.

If any of the following happen, stop taking Topicil and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, hives or fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Topicil. You may need urgent medical attention or hospitalisation. These side effects are very rare.

- severe skin reactions accompanied by fever and chills, aching muscles and generally feeling unwell.

These may be serious side effects of Topicil. You may need urgent medical attention. Serious side effects are uncommon.

Tell your doctor if you notice any other effects.

Other adverse effects not listed above may also occur in some patients.

After taking Topicil

Storage

Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack, they may not keep well.

Keep your capsules in a cool dry place where the temperature stays at or below 25°C.

Do not store Topicil in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

Topicil capsules are white/white hard capsules with markings of 'CLIN 150' on the capsule body. They are available as blister packs of 16, 24 or 100 capsules. Not all pack sizes may be marketed.

Ingredients

Active ingredient:

Clindamycin hydrochloride equivalent to 150 mg of clindamycin per capsule.

Inactive ingredients:

Talc, Magnesium stearate, Gelatin, Maize Starch, Lactose Monohydrate, Titanium dioxide (E171), Iron oxide black (E172) and Propylene glycol (E1520)

Sponsor details

Topicil is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

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