

Consumer Medicine Information

TOPICIL

Clindamycin hydrochloride

Capsules 150 mg

What is in this leaflet

Please read this leaflet carefully before you start using Topicil Capsules.

This leaflet answers some common questions about Topicil Capsules. 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 using Topicil Capsules against the benefits they expect it will have for you.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

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

What Topicil Capsules are used for

Topicil contains clindamycin, which belongs to a group of medicines called antibiotics. Antibiotics are used to treat infections. Topicil 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 this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

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

Topicil Capsules are not addictive.

Before you use Topicil Capsules

When you must not use it

Do not take Topicil Capsules:

1. if you have an allergy to:

- Clindamycin or lincomycin.
- Lactose or any of the other ingredients in Topicil Capsules. The other ingredients are listed at the end of this leaflet.

2. if the packaging is torn or shows signs of tampering

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

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

Before you start to use it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

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

Clindamycin crosses the placenta, therefore Topicil Capsules should be used in pregnancy only if clearly needed.

Do not breast-feed if you are taking this medicine.

The active ingredient in Topicil Capsules passes into breast milk and there is a possibility that your baby may be affected.

Check with your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- 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)
- severe liver or kidney problems
- asthma, hay fever or eczema
- lactose intolerance

Do not give Topicil Capsules to infants less than one month old.

There is not enough information to recommend the use of this medicine for infants under one month old.

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

Taking other medicines

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

Tell any health professional who is prescribing a new medicine for you that you are taking Topicil Capsules.

Some medicines and Topicil may interfere with each other. These include:

- Muscle relaxants used for operations and hospital procedures.
- erythromycin, an antibiotic used to treat infections.
- Oral contraceptive pills.

If you are taking the contraceptive pill, use additional contraception while taking Topicil Capsules, and for at least seven days after you have finished taking it. If in doubt, ask your doctor or pharmacist for advice.

The above medicines may be affected by Topicil Capsules, or may affect how well it works. You may need different amounts of Topicil, or you may need to take different medicines.

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

How to use Topicil Capsules

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet. You may be given a different dosage depending on your condition and how you react to the medicine.

How much to take

Adults

The standard adult dose is one to two capsules 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.

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.

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 the capsules until you finish the pack or until your doctor tells you to stop.

Do not stop taking Topicil Capsules because you are feeling better.

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

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.

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

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

While you are using Topicil Capsules

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.

Things you must not do

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

This medicine is only intended for the use of the patient it has been prescribed for. Do not take Topicil Capsules to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Topicil Capsules 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.

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. Take this leaflet and any tablets you still have with you. Your doctor will decide what measures are necessary.

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

If you take too many capsules, you may notice some of the following signs and symptoms of overdose:

- severe diarrhoea, usually with blood and mucous, stomach pain, fever (symptoms of pseudomembranous colitis, an inflammation of the large bowel)
- skin rash.

Side Effects

Check with your doctor or pharmacist as soon as possible if you have any problems while you are taking Topicil Capsules.

Like all medicines, Topicil Capsules may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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:

- nausea and/or vomiting
- itching of the skin
- taste disturbance or loss of taste.

These side effects are usually mild.

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

- stomach pain
- diarrhoea
- inflammation of the food pipe, or ulcers and/or pain in the food pipe; heartburn
- skin rash, hives, irritation of the skin

- jaundice (yellowing of the skin)
- vaginal thrush (discharge and itching in the vagina)
- painful or swollen joints.

These may be serious side effects. You may need urgent medical attention.

Also tell your doctor immediately if you develop the following symptoms while you are taking Topicil Capsules, or several weeks after you have finished taking it:

- severe stomach cramps or severe diarrhoea (sometimes with blood and mucous), in combination with fever.

These are symptoms of pseudomembranous colitis, an inflammation of the large bowel, which may require urgent medical care.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)
- severe skin reactions accompanied by fever and chills, aching muscles and generally feeling unwell.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

After using Topicil Capsules

Storage

Keep out of the reach and sight of children.

Do not use Topicil Capsules after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

Do not store above 25°C and store in the original package in order to protect from light.

Do not store Topicil Capsules or other medicines in the bathroom or near a sink. Do not leave the tablets in the car or on window sills. Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using Topicil Capsules or the capsules have passed their expiry date, ask your pharmacist how to dispose of any capsules no longer required.

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 size may be marketed.

Ingredients

Active ingredient(s):

- Clindamycin hydrochloride equivalent to 150 mg of clindamycin per capsule

Inactive ingredients:

- **Lactose**
- Maize starch
- Talc
- Magnesium stearate
- Gelatin
- Titanium dioxide (E171)
- Iron oxide black (E172)
- Propylene glycol (E1520)

Topicil Capsules contain lactose.

Sponsor Details

Topicil Capsules are supplied in New Zealand by:

Douglas Pharmaceuticals Limited
PO Box 45 027
Auckland 0651
NEW ZEALAND

ph: (09) 835 0660

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