

NEW ZEALAND CONSUMER MEDICINE INFORMATION

TILCOTIL®

Tenoxicam Film Coated Tablets 20 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Tilcotil.

This leaflet answers some common questions about Tilcotil.

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 Tilcotil 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 Tilcotil is used for

Tilcotil relieves pain and reduces inflammation (swelling, redness and soreness) that may occur in:

- different types of arthritis, including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. As with other NSAID medicines, Tilcotil will not cure your arthritic condition, but it may help to control pain, swelling and stiffness.
- muscle and bone injuries such as sprains, strains and tendonitis such as tennis elbow
- pain or swelling in or near a joint (bursitis)
- inflammation surrounding the shoulders (shoulder-hand syndrome) or hips

- degenerative joint disease (arthrosis)
- menstrual cramps (period pain)
- following surgery
- gout (a disease with painful, swollen joints)

Tilcotil contains the active ingredient tenoxicam. It belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Before you take Tilcotil

When you must not take it

Do not take Tilcotil if you have an allergy to:

- any medicine containing tenoxicam, aspirin or any other NSAID medicine
- 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 Tilcotil if you have:

- asthma
- had stomach or bowel problems after you have taken other NSAIDs
- a peptic ulcer (ulcer in the stomach or duodenum) or

- bleeding in your stomach, or have had this in the past
- a tendency to spontaneously bleed or bleed after minor accidents (haemorrhagic diathesis)
- severe heart, liver or kidney failure
- are more than six months pregnant (third trimester of pregnancy).

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.

Safety and effectiveness of Tilcotil have not been established for children and adolescents.

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

Before you start to take it

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

Tell your doctor if you have or have had any of the following medical conditions:

- liver or kidney disease
- diabetes
- high cholesterol
- heart failure, heart disease or uncontrolled blood pressure
- you have had a stroke
- you smoke (increases your risk of heart disease)
- you retain fluid
- a tendency to bleed
- visual disturbances
- an infection
- a history of inflammatory bowel disease (ulcerative colitis; Crohn's disease)

Tell your doctor if you have recently had or are about to have surgery.

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

Tilcotil may make it difficult to get pregnant and is not recommended in women trying to become pregnant. Tilcotil may affect you or your developing baby if you take it during pregnancy. Tilcotil is not recommended for use in the first and second trimester of pregnancy unless the benefits of treatment outweigh the risk to the unborn baby. Tilcotil must not be used in the third trimester of pregnancy

Do not take Tilcotil if you are in labour as it may harm you and/or affect the baby.

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

Tilcotil is not recommended while you are breastfeeding. If there is a need to consider taking Tilcotil while you are breastfeeding your doctor will discuss the risks and benefits of using it.

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

Taking other medicines

Tell your doctor or pharmacist 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 Tilcotil.

Some medicines may interfere with Tilcotil. These include:

- diuretics, also called fluid or water tablets
- oral medicines used to treat diabetes
- probenecid, a medicine used to treat gout
- antihypertensives, medicines used to treat high blood pressure

- corticosteroids used for inflammatory conditions such as betamethasone, dexamethasone, prednisone, triamcinolone, cortisone, methylprednisolone, prednisolone, hydrocortisone
- aspirin, salicylates or other NSAID medicines
- methotrexate, a medicine used to treat arthritis and some cancers
- lithium, a medicine used to treat some types of depression
- anticoagulant medicines used to prevent and treat blood clots such as warfarin, heparin, dabigatran
- selective serotonin reuptake inhibitors (SSRIs), a class of medicines used to treat some types of depression
- colestyramine, a medicine used to reduce cholesterol
- dextromethorphan, a medicine used to help soothe dry coughs and sore throats
- ciclosporin, a medicine used for transplant rejection episodes.

These medicines may be affected by Tilcotil or may affect how well it works. You may need different amounts of your medicines, 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 this medicine.

How to take Tilcotil

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

They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you how many Tilcotil tablets to take each day

depending on your condition. The usual dose is one 20 mg Tilcotil tablet once a day, however elderly patients or patients with kidney disease may need a lower dose.

However, for some conditions the dose may be different:

Period pain: the usual dose is one or two 20 mg Tilcotil tablets once a day.

Pain following surgery: the usual dose is two 20 mg Tilcotil tablets once a day for up to five days.

Attacks of gout: the usual dose is two 20 mg Tilcotil tablets once a day for two days, then one 20 mg Tilcotil tablet once a day for a further five days.

If you require long-term treatment, the daily dose may be reduced to half a 20 mg Tilcotil tablet (10 mg) once a day.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take Tilcotil tablets during or immediately after a meal.

If you take Tilcotil tablets on an empty stomach, they may cause stomach upset.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

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 medicine as you would normally.

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

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

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

While you are taking Tilcotil

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Tilcotil.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

If you get an infection while taking Tilcotil, tell your doctor. Tilcotil may hide some of the signs of an infection and may make you think, mistakenly, that you are better or it is not serious. Signs of an infection may include fever, pain, swelling and redness.

Tell your doctor if you have any eye (vision) problems, or if they develop while taking Tilcotil.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Tilcotil to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Tilcotil affects you.

This medicine may cause dizziness, light-headedness or vision problems in some people. If you have any of these symptoms, do not drive, 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, if you think that you or anyone else may have taken too much Tilcotil. 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 Tilcotil.

This medicine helps most people with pain and swelling, but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

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 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:

- stomach upset including nausea (feeling sick)
- heartburn, indigestion
- dizziness, light-headedness
- headache
- decreased appetite
- changes in sleep
- constipation
- diarrhoea
- flatulence
- vomiting
- dry mouth
- mouth ulcers
- rash
- tingling in the limbs
- confusion
- fatigue

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

- vomiting blood or material that looks like ground coffee
- bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- sudden swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- severe pain or tenderness in any part of the stomach
- severe skin reactions with blistering and/or severe rash or areas of unusually dark and swollen skin
- bruising or bleeding more easily than usual
- yellowing of the skin or whites of the eyes
- asthma, wheezing, shortness of breath
- pain or tightness in the chest
- eye problems such as blurred vision
- fast or irregular heartbeats, also called palpitations
- swelling of the hands, ankles or feet.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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

After taking Tilcotil

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Tilcotil or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Greyish yellow, oval, cylindrical, biconvex film-coated tablets with the imprint "20" on one side and a break-score on the other side.

Blister packs of 100 tablets.

Ingredients

Active ingredient:

Tilcotil contains 20 mg of tenoxicam as the active ingredient.

Inactive ingredient(s):

Tilcotil also contains:

- lactose
- maize starch
- talc
- magnesium stearate
- hypromellose
- titanium dioxide
- iron oxide yellow

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Tilcotil is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

27 June 2019

(Based on datasheet dated 14 June 2019)