

# New Zealand Consumer Medicine Information

## TILCOTIL<sup>®</sup>

*Tenoxicam 20 mg film coated tablets*

---

### What is in this leaflet

---

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 your taking TILCOTIL against the benefits expected 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 contains the active ingredient tenoxicam.

TILCOTIL belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

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)

Your doctor, however, may have prescribed TILCOTIL for another purpose.

**Ask your doctor if you have any questions why TILCOTIL 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:**

- 1. TILCOTIL or any ingredients listed at the end of this leaflet**
- 2. aspirin (e.g. Aspro<sup>®</sup>, Disprin<sup>®</sup>, Cartia<sup>®</sup>)**
- 3. any other NSAID medicine, which may include ibuprofen (Brufen<sup>®</sup>, Nurofen<sup>®</sup>, Panafen<sup>®</sup>), mefenamic acid (Ponstan<sup>®</sup>), diclofenac sodium (Voltaren<sup>®</sup>, Cataflam<sup>®</sup>, Apo-Diclo<sup>®</sup>, Diclax<sup>®</sup>, Flameril<sup>®</sup>), naproxen (Naprosyn<sup>®</sup>, Synflex<sup>®</sup>, Naprogesic<sup>®</sup>), indomethacin (Indocid<sup>®</sup>, Rheumacin<sup>®</sup>), celecoxib (Celebrex<sup>®</sup>), ketoprofen (Orudis<sup>®</sup>, Oruvail<sup>®</sup>), sulindac (Daclin<sup>®</sup>), tiaprofenic acid (Surgam<sup>®</sup>), meloxicam (Mobic<sup>®</sup>), etoricoxib (Arcoxia<sup>®</sup>)**

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting
- blocked or running nose

**If you are allergic to aspirin or NSAID medicines and take TILCOTIL, these symptoms may be severe.**

**Do not take TILCOTIL if:**

- 1. you have asthma**
- 2. you have a peptic ulcer (ulcer in the stomach or duodenum), or have had a peptic ulcer in the past**

3. **you have, or have had, a stomach problem causing pain, nausea, vomiting, vomiting blood and/or blood in the bowel motions**
4. **you have a tendency to spontaneously bleed or bleed when incurring minor accidents (haemorrhagic diathesis)**
5. **you have severe liver or kidney disease**
6. **you have severe heart failure**
7. **You are in the third trimester of pregnancy**

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

**Do not take TILCOTIL if the expiry date printed on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

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

---

## **Before you start to take it**

---

### ***Tell your doctor if:***

1. **you are pregnant or plan to become pregnant**

TILCOTIL may make it difficult to get pregnant and is not recommended in women trying to get 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.

2. **you are breast-feeding or intend to breast-feed**

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

3. **you have or have had any medical conditions, especially the following:**

- liver disease
- kidney disease
- diabetes

- a tendency to bleed
- heart failure or heart disease or uncontrolled blood pressure
- you have had a stroke
- you smoke (increases the risk of heart disease)
- you retain fluid
- you have high cholesterol
- history of inflammatory bowel disease (ulcerative colitis; Crohn's disease)

**4. you have recently had or are about to have major surgery**

**5. you currently have an infection**

If you take TILCOTIL while you have an infection, it may hide some of the signs of an infection (eg. pain, fever). This may make you think, mistakenly, that you are better or the infection is not serious.

**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 if you are taking any other medicines, including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with TILCOTIL. These include:

- diuretics, also called fluid or water tablets
- diabetic medicines taken by mouth, medicines used to treat diabetes
- probenecid, a medicine used to treat gout
- corticosteroids - betamethasone, dexamethasone, prednisone, triamcinolone, cortisone, methylprednisolone, prednisolone, hydrocortisone, fludrocortisone
- aspirin, salicylates or other NSAID medicines
- methotrexate (Methoblastin<sup>®</sup>), a medicine used to treat arthritis and some cancers
- lithium (Lithicarb<sup>®</sup>, Priadel<sup>®</sup>), a medicine used to treat some types of depression
- anticoagulant medicines - warfarin (Coumadin<sup>®</sup>, Marevan<sup>®</sup>), heparin (Clexane<sup>®</sup>, Fragmin<sup>®</sup>, Innohep<sup>®</sup>, Monoparin<sup>®</sup>, Multiparin<sup>®</sup>), dabigatran (Pradaxa<sup>®</sup>), apixaban (Eliquis<sup>®</sup>), rivaroxaban (Xarelto<sup>®</sup>). medicines used to stop blood clots
- selective serotonin reuptake inhibitors (SSRI's) - a class of medicines used to treat some types of depression (eg: Aropax<sup>®</sup>, Cipramil<sup>®</sup>, Prozac<sup>®</sup>)
- antihypertensives, medicines used to treat high blood pressure
- Ciclosporin, used for transplant rejection episodes

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

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

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

---

## **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.

### ***How much to take***

**Take TILCOTIL exactly as your doctor has prescribed.**

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 TILCOTIL***

Swallow TILCOTIL tablets whole with a glass of water. Do not chew the tablet.

### ***When to take TILCOTIL***

**TILCOTIL should be taken once daily, at about the same time each day.**

**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 TILCOTIL***

Your doctor will advise you on how long you need to take TILCOTIL tablets for.

---

## **If you forget to take TILCOTIL**

---

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 it as you would normally.

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

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

---

## **If you take too much (overdose)**

---

**Immediately telephone your doctor, or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to your nearest Accident and Emergency Centre if you think 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.

The following are some symptoms which may or may not occur:

- pain or tenderness in the stomach
- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion or cramps
- difficulty breathing

**Keep telephone numbers for these places handy.**

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

---

## **While you are taking TILCOTIL**

---

### ***Things you must do***

**Tell all doctors, dentists and pharmacists who are treating you that you are taking TILCOTIL.**

**Tell your doctor if you become pregnant while taking TILCOTIL.**

**If you are going to have surgery tell your surgeon you are taking TILCOTIL.**

**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.

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**Tell your doctor if you feel that TILCOTIL is not helping your condition.**

**Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

Your doctor may wish to perform tests from time to time to monitor your condition.

---

## **Things you must not do**

---

Do not stop taking TILCOTIL or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

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

Do not use TILCOTIL to treat other complaints unless your doctor says to.

Do not take other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

---

## **Things to be careful of**

---

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

As with other NSAID medicines, TILCOTIL may cause dizziness, light-headedness or vision problems in some people. Make sure you know how you react to TILCOTIL before you drive a car, operate machinery, or do

anything else that could be dangerous if you are dizzy or light-headed, or your vision is altered. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

---

## Side Effects

---

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

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 if you notice any of the following and they worry you:**

- stomach upset including nausea (feeling sick), heartburn, indigestion
- dizziness, lightheadedness
- headache

**Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:**

- 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
- 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

**These are serious side effects. You may need urgent medical attention.**

The most common side effects are dyspepsia, nausea, abdominal pain, dizziness or headaches.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on these lists.**



**Ask your doctor or pharmacist if you don't understand anything in these lists.**

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

---

## **After taking TILCOTIL**

---

### ***Storage***

**Keep your TILCOTIL in the original packaging until it is time to take it.**

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

**Keep the tablets in a cool, dry place where the temperature does not go above 30°C.**

**Do not store TILCOTIL or any other medicine in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep TILCOTIL 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 TILCOTIL, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

---

## **Product Description**

---

### ***Availability***

TILCOTIL 20 mg tablets come in packs of 100.

### ***What TILCOTIL 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.

---

## **Ingredients**

---

**Active ingredient**

Tenoxicam

- each TILCOTIL tablet contains 20 mg tenoxicam

### **Inactive ingredients**

Lactose, maize starch, talc, magnesium stearate, hypromellose, titanium dioxide (E171) and iron oxide yellow (CI77492, E172)

---

## **Sponsor**

---

Mylan New Zealand Ltd  
PO Box 11183  
Ellerslie  
Auckland.

Telephone: (09) 579 2792

---

## **Date of Preparation**

---

20 December 2016

(based on the Tilcotil datasheet dated 5 December 2016)