

FUNGILIN® Lozenges

amphotericin B

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking Fungilin Lozenges. This leaflet answers some common questions about Fungilin.

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 Fungilin against the benefits they expect it will have for you.

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

Always follow the instructions that your doctor or pharmacist gives you about Fungilin Lozenges.

Keep this leaflet with the medicine.

You may need to read it again.

What Fungilin is used for

Fungilin is a trade name (manufacturer's name) for the antifungal medicine, Amphotericin B. Fungilin Lozenges are used to treat infections in or around the mouth, throat or tongue caused by yeast-like fungi called *Candida*. This condition is known as oral candidiasis or thrush. *Candida albicans* is the most common cause of thrush.

C. albicans is present in the gut of both men and women, and often in women's vaginas without causing problems. When conditions are suitable for its growth, *C. albicans* will multiply and cause infection.

A number of different conditions provide favourable growth conditions for *Candida*, such as Acquired Immune Deficiency Syndrome (AIDS), diabetes, treatment with some antibiotic or cortisone medicines, or treatment for cancer.

Fungilin is not expected to affect your ability to drive a car or operate machinery. Fungilin Lozenges are tolerated well by all age groups.

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

Before you take Fungilin

It is important that you check the information below before you take Fungilin Lozenges.

When you must not take them

Do not take Fungilin if you have an allergy to it or to any ingredients in the formulation listed at the end of this leaflet.

Do not take it after the expiry date printed on the back of the pack. If this medicine is used after the expiry date has passed, it may not work as well.

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

Before you start taking it

Tell your pharmacist if:

- you have allergies to:**
 - Amphotericin B or to any ingredients in the formulation listed at the end of this leaflet;
 - any other medicines; substances such as foods, preservatives or dyes.Symptoms of an allergic reaction may include:
 - swelling of the face, tongue, mouth, lips, throat and difficulty breathing
 - severe and sudden onset of hives or a skin rash.
- you are pregnant or intend to become pregnant. Fungilin is not recommended for use during pregnancy unless the benefits of treatment outweigh the risks to the unborn baby.**
- you are breast-feeding or planning to breast-feed. It is not known whether Fungilin passes into breast milk.**
- you have or have had any medical conditions. If you have diabetes, consult with your doctor first before taking Fungilin Lozenges.**

If you have not told your pharmacist about any of the above, tell them before you start to take Fungilin Lozenges.

Taking other medicines

Tell your pharmacist if you are taking other medicines, including vitamin and herbal supplements or any medicines you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while using Fungilin.

How to take Fungilin

Use Fungilin only as directed by your doctor or pharmacist. It is important that you always follow your doctor's or pharmacist's instructions as they may differ from the information in this leaflet.

How much to take

The recommended daily dose of Fungilin Lozenges is one lozenge, taken four times daily.

How to take it

Suck the lozenge and allow it to dissolve slowly in the mouth.

If you wear dentures, take them out while sucking the lozenge. This allows the medicine to reach where the dentures normally fit. Before replacing your dentures, clean them thoroughly.

If you do not understand the instructions on how to take Fungilin Lozenges, ask your pharmacist for help.

When to take it

Take Fungilin at about the same time each day, after meals and at bedtime. Taking Fungilin Lozenges at the same time each day will have the best effect and may help you remember when to take the Lozenges.

How long to take it

Continue taking Fungilin Lozenges for 10-15 days.

If your symptoms do not improve after several days of treatment or they return soon after completing your course of treatment, tell your doctor. This may be a sign that your infection is caused by an organism which is resistant to Fungilin Lozenges or, you may have another underlying condition of which you are not aware.

Therefore, it is very important that you advise your doctor if the condition persists after following the recommended course of treatment. Your doctor may request that you have additional tests to further diagnose and treat your condition.

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 and then go back to taking it as you would normally.

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

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

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

If you take too much (overdose)

Taking too many Fungilin Lozenges is unlikely to cause problems. Immediately call your doctor, or the Poisons Information Centre on 03 474 7000 or go to the Accident and Emergency Centre at your nearest hospital if you or anyone else accidentally takes too much Fungilin. Do this even if there are no signs of discomfort or poisoning.

While you are taking Fungilin

Things you must do

If you are about to start taking any new medicines, tell all doctors and pharmacists who are treating you that you are taking Fungilin Lozenges.

If you become pregnant while using Fungilin Lozenges, tell your doctor immediately.

If you plan to have surgery, tell your doctor or dentist that you are taking Fungilin Lozenges.

If your symptoms do not improve while you are taking Fungilin or they become worse, tell your doctor.

Things you must not do

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

Fungilin Lozenges are intended for mouth infections only, caused by *Candida* yeast infections. Do not take Fungilin Lozenges to treat any other complaints unless your doctor or pharmacist tells you to.

Unless you experience a bad side effect or allergic reaction to Fungilin Lozenges, do not stop using Fungilin Lozenges until the infection is cured.

Things that may help your condition

To avoid the possibility of re-infection or infection of other household members, you must observe strict personal hygiene. Hands must be washed thoroughly before and after taking the lozenges.

Wash used kitchen utensils by boiling for 20 minutes. Wash your used utensils separately and keep them away from utensils used by other household members. This may help prevent spread of the infection.

If you have yellowing of the teeth while using Fungilin, this can be removed by brushing your teeth.

Side effects

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

Fungilin Lozenges helps most people with *Candida* infections, but it may have unwanted side effects in a few people.

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 pharmacist to answer any questions you may have.

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

- hives,
- swelling of the face, mouth, lips, tongue or throat and have difficulty breathing

These are very serious side effects. If you have them, you may have had an allergic reaction to Fungilin Lozenges. You may need urgent medical attention. All of these side effects are very rare.

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

- diarrhoea
- indigestion or upset stomach
- nausea
- vomiting
- yellowing of the teeth (which can be removed by brushing the teeth).

These are the more common side effects of Fungilin Lozenges. Mostly these are mild and short-lived.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything 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 Fungilin

Storage

Keep your Fungilin Lozenges in the pack until it is time to take them. If you take them out of bottle they may not keep as well.

Store Fungilin Lozenges in a cool dry place where the temperature stays below 25°C.

Do not store Fungilin Lozenges or any other medicine in the bathroom or near the kitchen sink. Do not leave it 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 using Fungilin Lozenges, or the lozenges have passed their expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Fungilin Lozenges are round, yellow-coloured, fruit-flavoured lozenge.

Ingredients

Each lozenge contains:

Active ingredients:
Amphotericin B

Other ingredients:

- mannitol,
- acacia,
- stearic acid,
- sodium cyclamate,
- sodium saccharin,
- polyvinyl alcohol,
- talc,

- blood orange flavour,
- curacao, and
- natural orange flavour.

Fungilin Lozenges do not contain lactose, gluten, tartrazine or any other azo dyes.

Presentation

Fungilin Lozenges (10mg Amphotericin B lozenge) are available in packs containing 20 lozenges. AUST R 19295.

Sponsor/Supplier

Aspen Pharma Pty Ltd
34-36 Chandos St
St Leonards
2065 NSW

This information in no way replaces the advice of your doctor or pharmacist.

This leaflet was revised in April 2012.