Simplotan* tablets

Tinidazole (tin-id-azole)

Consumer Medicine Information

What is in this leaflet

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

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

Read this leaflet carefully before starting Simplotan and keep it with your medicine.

You may need to read it again.

What Simplotan is used for

Simplotan is used to

- treat certain infections of the male and female genital systems, liver and bowel
- prevent certain infections that may occur during surgery.

Simplotan is an antibiotic, which belongs to a group of medicines called nitroimidazoles.

Simplotan works by killing or stopping the growth of bacteria causing your infection.

Simplotan will not work against viral infections such as colds or flu.

Your doctor, however, may prescribe Simplotan for another purpose.

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

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

Before you take Simplotan

When you must not take it

Do not take Simplotan if you are allergic to:

- Simplotan
- any ingredients listed at the end of the leaflet
- or related medicines such as Fasigyn, Flagyl, Metrogyl and Metozine (not all brands given)

If you are not sure if you are allergic to any of the above, ask your doctor.

Symptoms of an allergic reaction include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing
- hives, itching or skin rash
- fainting.

Do not take Simplotan if you have a history of any blood disorder.

Do not take Simplotan if you have any disease of the brain, spinal cord or nerves.

Do not take Simplotan if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of taking Simplotan during pregnancy (pregnancy up to four months).

If you are a woman of child-bearing age, make sure you do not become pregnant while taking Simplotan.

Do not take Simplotan if you are breastfeeding.

Like many other medicines, Simplotan passes into breast milk and may harm your baby.

Do not breastfeed your baby while taking, and until at least three days after stopping Simplotan.

If you are not sure whether you should be taking Simplotan, talk to your doctor.

Do not take Simplotan if the expiry date (EXP) or use by date printed on the pack has passed.

If you take this medicine after this date, it may not work.

Do not take Simplotan if the packaging is torn or shows signs of tampering. If this is the case, return it to your pharmacist.

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

Before you start to take it

You must tell your doctor if:

1. **you have any allergies to:**
   - any other medicines
   - any other substances, such as foods, preservatives or dyes
2. **you are pregnant or intend to become pregnant**

Like most other medicines, Simplotan is not recommended in pregnancy. However, your doctor will discuss the possible risks and benefits of taking Simplotan during pregnancy.

3. **you are breastfeeding or plan to breast-feed**

   Like most other medicines, Simplotan is not recommended in breast-feeding. However, your doctor will discuss the possible risks and benefits of taking Simplotan during breast-feeding.

4. **you have or have had any other medical conditions, including any kidney problems**
5. **you drink alcohol, even occasionally. Do not drink during and for 3 days after stopping treatment with Simplotan.**

   If you drink alcohol with Simplotan it may make you feel sick, vomit, have stomach cramps, headache or flushing.

If you have not told your doctor about any of the above, tell them before you are given Simplotan.

Taking other medicines

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

Some medicines may interfere with Simplotan. These include:

- warfarin or other medicines used to prevent blood clots

These medicines may be affected by Simplotan or may affect how well it works.

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

Do not take medicines that contain alcohol (eg cough syrups) while using, or for three (3) days after stopping Simplotan.

Talk to your doctor about the need for an additional method of contraception while taking Simplotan.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with Simplotan.

How to take Simplotan

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 pack, ask your doctor or pharmacist for advice.

How much to take

Adults

Simplotan is usually given as a single dose of four tablets, to be taken at the same time.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take some other dose or take it for a longer time.

Children

For children, the dose depends on body weight.

How long to take

Your doctor will tell you how long you need to keep taking Simplotan.

In some cases, you may need to take Simplotan for up to ten days.

How to take it

Swallow the tablets with liquid.

When to take it

Take Simplotan during or immediately after a meal.

If taken on an empty stomach, it may cause stomach upset.

If you forget to take it

If you are taking more than a single dose of Simplotan and 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, then go back to taking it as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of you getting an unwanted side effect.

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone in Australia - 13 11 26) for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much Simplotan. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers of these places handy.

If you take too many tablets, you may get an upset stomach, diarrhoea or skin rashes.

While you are taking Simplotan

Things you must do

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

If you get a sore, white mouth or tongue while taking, or soon after stopping Simplotan, tell your doctor or pharmacist.

If you get vaginal itching, burning or a white discharge while taking, or soon after stopping Simplotan, tell your doctor or pharmacist.

This may mean you have a yeast infection called thrush. Sometimes use of Simplotan allows yeast to grow and the above symptoms to occur. Simplotan does not work against yeast.

If you are about to start taking any new medicines, tell your doctor or pharmacist that you are taking Simplotan.

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

Things you must not do

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

Do not use Simplotan to treat any other medical complaints unless your doctor tells you to.

Side effects

Check with your doctor as soon as possible if you have any problems while taking Simplotan, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Simplotan can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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:

- generally feeling unwell
- a metallic taste in the mouth
- loss of appetite, feeling sick, stomach pain, diarrhoea or constipation
- dark coloured urine
- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge

These side effects are usually mild.

See your doctor immediately and before you take your next dose of Simplotan if you notice any of the following:

- asthma, wheezing or shortness of breath
- hives, itching or skin rash
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing
- fainting
- tingling or numbness of the hands or feet, or muscle weakness

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

- headache, dizziness, a spinning sensation, shaky or unsteady movements
- unusual tiredness or flu-like illness

These side effects are rare but may be serious and need urgent medical attention.

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

Tell your doctor if you notice any other effects.

After using Simplotan

Storage

Keep Simplotan in its original packaging until it is time to use it.

If you take Simplotan out of its packaging, it may not keep as well.

Keep your Simplotan in a cool, dry place where it stays below 25 degrees Celsius.

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

Heat and dampness can destroy some medicines.

Keep your Simplotan where young children cannot reach it.

A locked cupboard at least 1 1/2 metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Simplotan, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

White, round tablets marked FAS 500 on one side and plain on the other, in packs of four.

Ingredients

Simplotan contains 500mg of tinidazole per tablet as the active ingredient. It also contains:

- microcrystalline cellulose
- alginic acid (400)
- maize starch
- magnesium stearate (470)
- sodium lauryl sulfate
- hypromellose
- propylene glycol (1520)
- titanium dioxide

Manufacturer

Simplotan is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW 2000

Australia

Toll free number: 1800 675 229

Australian Registration Number:

AUST R 48964

This leaflet was revised on
November 2019.

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