

ATARIS® 10 & ATARIS® 20

leflunomide

Consumer Medicine Information

Please read this leaflet carefully before you start ATARIS 10 or ATARIS 20.

What is in this leaflet

This leaflet answers some common questions about ATARIS.

It does not contain all of 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 ATARIS 10 or ATARIS 20 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 ATARIS is used for

ATARIS is a type of medicine used to treat rheumatoid or psoriatic arthritis. ATARIS helps to slow down the process of joint damage and to relieve the symptoms of the disease, such as joint tenderness and swelling, pain and morning stiffness.

ATARIS works by selectively interfering with the ability of white blood cells called lymphocytes to produce the disease response that ultimately leads to pain, inflammation and joint damage.

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

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

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

Before you take ATARIS

When you must not take it

Do not take ATARIS if you:

- **have any diseases which reduce your body's natural defences such as bacterial or viral infections**
- **an illness which severely lowers your body's resistance to disease, such as AIDS**
- **have any diseases of the blood or bone marrow, such as anaemia**
- **have any serious skin disorders, such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme**
- **have liver disease**
- **have a condition called hypoproteinaemia (when you do not have enough protein in your blood)**
- **are pregnant or plan to become pregnant**
- **are not using reliable birth control**
- **are breastfeeding**

You must not become pregnant while taking ATARIS and for a

certain period of time after stopping ATARIS.

ATARIS may increase the risk of birth defects.

If there is any delay in the onset of menses or you suspect you are pregnant, notify your doctor immediately to test for pregnancy.

Women of childbearing potential must use reliable contraception while taking ATARIS and for a certain period of time after you have stopped taking it.

Do not take it if you are breastfeeding or planning to breastfeed.

ATARIS passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not take ATARIS if you are allergic to leflunomide, teriflunomide, or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give ATARIS to a child or adolescent.

ATARIS is not approved for use in children or adolescents under 18 years old.

Do not take it 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.

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

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

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes.

Tell your doctor immediately if you think you could be pregnant while taking ATARIS.

Tell your doctor if you intend to become pregnant or father a child. ATARIS may increase the risk of birth defects. To reduce any risk to the developing baby, you will need to stop taking ATARIS and may need to undergo a wash-out procedure. Your doctor will discuss the wash-out procedure with you.

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

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

- a decrease in the number of white blood cells
- liver problems
- kidney problems
- chronic (ongoing) infections
- an illness which lowered your body's resistance to disease
- peripheral neuropathy
- tuberculosis
- diabetes
- are taking neurotoxic agents
- a history or have a family history of lung problems, such as interstitial lung disease (an inflammation of lung tissue) which is a serious and potentially fatal disease

Tell your doctor if you plan to have surgery.

Tell your doctor if you have recently been vaccinated or if you need to have a vaccination during treatment

with this medicine or for 6 months after stopping ATARIS.

Live vaccines should be avoided while taking this medicine.

If you have not told your doctor about any of the above, tell them before you take ATARIS.

Taking other medicines

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

Some medicines may interfere with ATARIS. These include:

- teriflunomide, a medicine similar to leflunomide
- warfarin, a medicine used to stop blood clots
- ibuprofen, naproxen and diclofenac, amiodarone, batroxobin, captopril
- teriflunomide, a medicine similar to leflunomide
- duloxetine, used to treat depression
- theophylline, used to treat respiratory conditions such as asthma
- furosemide, a diuretic
- zidovudine, an antiretroviral
- some medicines used for diabetes (e.g. tolbutamide, repaglinide, nateglinide, pioglitazone or rosiglitazone)
- some medicines used to treat epilepsy (e.g. phenytoin)
- antibiotics such as rifampicin, cefaclor, benzylpenicillin and ciprofloxacin
- medicines used in cancer treatment such as paclitaxel, topotecan, daunorubicin and doxorubicin
- some medicines used to treat cholesterol such as colestyramine and statins (e.g. rosuvastatin, simvastatin, atorvastatin or pravastatin)

- NSAIDs (non-steroidal antiinflammatory drugs), such as indomethacin or ketoprofen
- methotrexate and sulfasalazine, used to treat autoimmune disorders such as rheumatoid arthritis
- some types of oral contraceptives
- medicines which have side effects on the blood
- alosetron, used to treat irritable bowel syndrome
- tizanidine, used as a muscle relaxant
- cimetidine, used to treat heart burn and reflux
- some medicines used for tuberculosis (TB)

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

In certain situations, for example, if you experience a serious side effect, you change your medication or you want to fall pregnant, your doctor will ask you to take medication that will help your body get rid of ATARIS faster.

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

How to take ATARIS

How much to take

Your doctor will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

The standard dose for this medicine is one 100mg tablet per day for the first 3 days, and after that one 10mg or 20mg tablet daily.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

These directions may differ from the information contained in this leaflet. If you take the wrong dose, ATARIS may not work as well.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

It does not matter if you take ATARIS before or after food.

Take ATARIS at about the same time each day.

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

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

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

The medicine helps control your condition, but it does not cure it. Therefore, you must take it every day.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

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

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

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much ATARIS.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include diarrhoea, stomach pain, changes in blood, or liver damage.

While you are using ATARIS

Things you must do

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

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

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

This medicine may cause serious birth defects.

Tell your doctor before stopping contraception. You must continue using appropriate reliable contraception (the 'Pill' or condoms) while you are taking ATARIS.

If you plan to stop your contraception, you must first discuss this with your doctor.

If you have an infection or notice a fever or signs of an infection while taking this medicine, tell your doctor immediately.

Tell your doctor if you develop symptoms such as pins and needles or tingling in the hands or feet or numbness or weakness of the arms and legs, or become clumsy, have visual problems and problems speaking.

If your skin becomes itchy or yellow, if the whites of your eyes become yellow, or if you start to bleed or bruise easily, stop taking it and tell your doctor or pharmacist immediately.

You may be developing a liver problem. Your doctor may need to take blood samples to monitor the health of your liver and blood cells while you are taking ATARIS.

Tell your doctor immediately if you develop new or worsening symptoms such as a cough or trouble breathing.

Inflammation of the lung tissue which can be fatal, has been reported in some patients.

Tell your doctor immediately and stop taking your medicine if you develop any symptoms of liver problems, including yellowing of eyes, itchy and yellowing skin, bruising and bleeding easily.

Your doctor will check the health of your liver using blood tests on a regular basis while you are taking ATARIS.

Tell your doctor if you need to have a vaccination during treatment with this medicine or for 6 months after stopping treatment.

Tell your doctors if you are going to have surgery or an anaesthetic or are going into hospital.

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

Your doctor will do blood tests and monitor your blood pressure before starting and during treatment. This is to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

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

Do not use this medicine to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

The effects of alcohol could be made worse while taking ATARIS. It is recommended that you minimise your alcohol intake while taking ATARIS.

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

This medicine may cause tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

It helps most people with arthritis, but it may have unwanted side effects in a few people.

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

- diarrhoea
- nausea, vomiting, abdominal pain
- rashes, itchy skin
- hair loss
- weight loss
- unusual tiredness or weakness

- joint, muscle and general pain
- varicose veins
- constipation
- dry mouth
- problems sleeping
- headache
- dizziness
- sweating
- blurred vision
- changes in taste
- pins and needles sensation in hands or feet

These are the more common side effects of ATARIS Tablets.

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

- signs and symptoms of severe infection e.g. fever
- severe upper stomach pain, often with nausea and vomiting, anorexia, or diarrhoea
- joint pain, swelling, stiffness, muscle weakness
- problems with tendons in the legs
- severe skin rash, scaling or sores and blisters (sometimes in your mouth including ulcers), often with flu-like symptoms
- your skin becomes pale, you start to feel tired, you become prone to infections or bruising
- if you develop new or worsening symptoms such as cough or trouble breathing, with or without a fever, blisters and bleeding in the lips, eyes, mouth, nose and genitals
- thickened patches of red skin
- irregular, fast or slow heartbeat
- shortness of breath, tiredness, swelling in the legs, dizziness
- chest pain
- dark stools
- blood in the urine
- excessive thirst, frequent urination or decreased urine
- anxiety, depression, delirium, confusion

- changes to your liver and pancreas or blood, which may be detectable by blood tests
- temporary changes to sperm

These may be serious side effects of ATARIS. You may need urgent medical attention. Serious side effects are uncommon.

ATARIS decreases your body's immune response and can cause some of the side effects listed above.

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

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- hives
- fainting
- yellowing of the skin and eyes (jaundice)

These are very serious side effects. If you have them, you may have had a serious allergic reaction to ATARIS.

You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

Other side effects not listed above may occur in some consumers.

Ask your doctor or pharmacist to answer any questions you may have.

After using ATARIS

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

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

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

Do not store it or any other medicine in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

If your doctor or pharmacist tells you to stop taking ATARIS tablets or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

Tablets, film coated

10 mg: white, round biconvex tablets
30's (bottle);

20 mg: yellow, round biconvex
tablets with a scoreline on one side
30's (bottle);

Ingredients

Active: Leflunomide

Inactive:

- microcrystalline cellulose
- lactose monohydrate
- maize starch
- povidone
- crospovidone
- colloidal anhydrous silica
- magnesium stearate

The 10 mg tablets also contain
Opadry II complete film coating
system OY-LS-28908 White

The 20 mg tablets also contain
Opadry aqueous film coating OY-
SR-6497 Yellow.

ATARIS 10 mg and 20 mg tablets
contain sugars as lactose.

Sponsor

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Registration Number:

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ATARIS 10

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ATARIS 20

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