Arabloc®

leflunomide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Arabloc.

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 Arabloc 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 Arabloc is used for

Arabloc is a type of medicine used to treat rheumatoid or psoriatic arthritis. Arabloc 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.

Arabloc 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 Arabloc 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 it

When you must not take it

Do not take Arabloc if you:

- **have any diseases which reduce your body's natural defences such as bacterial or viral infections**
- **have any diseases of the blood**
- **have any serious skin disorders**
- **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 Arabloc and for a certain period of time after stopping Arabloc.

Arabloc may increase the risk of birth defects.

Women of childbearing potential must use reliable contraception while taking Arabloc.

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

Arabloc passes into breast milk and therefore there is a possibility that the breastfed baby may be affected.

Do not take Arabloc if you are allergic to it 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 Arabloc to a child or adolescent.

Arabloc 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.

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 Arabloc.

Tell your doctor if you intend to become pregnant or father a child.

Arabloc may increase the risk of birth defects. To reduce any risk to the developing baby, you will need to stop taking Arabloc 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 infections
- an illness which lowered your body's resistance to disease
- tuberculosis
- 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.

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

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 Arabloc. These include:

- warfarin, a medicine used to stop blood clots
- some medicines used for diabetes
- some medicines used to treat epilepsy
- some medicines used for tuberculosis (TB)

These medicines may be affected by Arabloc, 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 Arabloc faster.

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

How to take it

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 100 mg per day for the first 3 days, and after that one 10mg or 20 mg 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, Arabloc 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 Arabloc before or after food.

Take Arabloc 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 Arabloc.

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

You may need urgent medical attention.

While you are taking it

Things you must do

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

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

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

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

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

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 Arabloc.

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 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.

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

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 Arabloc, or lower the dosage, without checking with your doctor.

Things to be careful of

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

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 Arabloc.

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
- rashes, itchy skin
- hair loss
- weight loss
- unusual tiredness or weakness

These are the more common side effects of Arabloc.

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 eg. fever
- severe upper stomach pain, often with nausea and vomiting
- severe skin rash or sores in your mouth
- 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.

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

Arabloc 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)**
- **thickened patches of red skin**

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

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

You may not experience any of them.

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

After taking it

Storage

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 25°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.

Disposal

If your doctor or pharmacist tells you to stop taking Arabloc 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

What it looks like

Arabloc 10 mg tablets are white to almost white, round film-coated tablets with the embossing ZBN. Arabloc 10mg tablets are supplied in bottles in packs of 10# and 30 tablets.

Arabloc 20 mg tablets are yellowish to ochre, spherical triangular film-coated tablets with the embossing ZBO. Arabloc 20mg tablets are supplied in bottles in packs of 10# and 30 tablets.

Arabloc 100 mg tablets are white to almost white, round film-coated tablets with the embossing ZBP. Arabloc 100mg tablets are supplied in blisters in packs of 3#.

Presentations currently not marketed.

Ingredients

Active Ingredient:

Each tablet contains 10 mg, 20mg or 100 mg of the active ingredient, leflunomide.

Inactive Ingredients:

- lactose
- maize starch
- povidone
- colloidal anhydrous silica
- magnesium stearate
- crospovidone
- hypromellose
- macrogol 8000
- talc and titanium dioxide
- iron oxide yellow (20 mg tablet only)

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

Manufacturer/Sponsor

Arabloc is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Arabloc is supplied in New Zealand by:

sanofi -aventis new zealand limited

Level 8, James and Wells Tower

56 Cawley Street

Ellerslie

Auckland

Australian Registration Number(s):

10 mg : AUST R 92753

20 mg : AUST R 92754

100mg: AUST R 92755

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