

YONSA[®] MPRED

Abiraterone acetate and methylprednisolone

125 mg tablet and 4 mg tablet

What is in this leaflet

Please read this leaflet carefully before you start using YONSA MPRED.

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

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

Keep this leaflet with the medicine. You may need to read it again.

What YONSA MPRED is used for

YONSA MPRED is a combination pack which contains two different medicines, YONSA tablets and Methylprednisolone tablets. YONSA tablets contain the active ingredient abiraterone acetate and Methylprednisolone tablets contain the active ingredient methylprednisolone.

Abiraterone acetate works by reducing the levels of male sex hormones in your body, including testosterone.

Methylprednisolone is a corticosteroid that must be taken to reduce the chance of developing low blood pressure, heart effects or low levels of potassium in your blood while you are using YONSA tablets.

YONSA MPRED is used to treat prostate cancer that has spread to other parts of the body.

Your doctor may have prescribed YONSA MPRED for another reason.

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

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

Before you use YONSA MPRED

When you must not use it

Do not use YONSA MPRED if:

- You are allergic to abiraterone acetate, methylprednisolone or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- If you are pregnant or may potentially be pregnant.

If you are not sure whether you should start using YONSA MPRED, talk to your doctor.

Before you start to use it

Check with your doctor if you have any other medical conditions, especially the following:

- Problems with your liver and kidneys
- High blood pressure
- Heart problems
- Low levels of potassium in your blood
- Fluid retention (bloating, swollen legs, feet, ankles, puffiness in the abdomen, face and hips, sudden unexplained increase in weight)
- Tuberculosis
- Underactive thyroid gland
- Herpes in the eye
- Hypoprothrombinaemia (a blood clotting disorder)
- Disease of the bowel e.g. ulcerative colitis or diverticulitis
- Stomach ulcers
- Diabetes
- Cushing's disease (a hormonal disorder)
- Seizures/epilepsy
- Myasthenia gravis (ongoing muscle weakness and chronic fatigue)
- Thin or weak bones
- Blood clots
- Systemic sclerosis
- Problems digesting or tolerating sugars such as lactose
- Take any medicine for any other condition

Pregnancy and breast feeding

Do not take YONSA MPRED if you are pregnant or may potentially be pregnant.

YONSA MPRED is not for use in women and children.

Problems with your liver

You should not take YONSA MPRED if you have moderate or severe liver disease.

Your doctor will decide whether YONSA MPRED can be used if you have a mild liver problem.

YONSA MPRED may affect your liver. When you are taking YONSA MPRED your doctor will check your blood to look for any effects on your liver.

High blood pressure and heart problems

YONSA can make high blood pressure or heart failure or low blood potassium worse.

Taking methylprednisolone with YONSA helps to avoid worsening of these conditions. If you have these conditions or other heart or blood vessel problems, discuss them with your doctor.

If you have not told your doctor about any of the above, tell them before you start using YONSA MPRED.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking YONSA MPRED.

Some medicines may interfere with YONSA MPRED. These include:

- Medicines for bacterial infections (antibiotics) such as rifampicin, erythromycin, clarithromycin and isoniazid
- Cough medicines such as dextromethorphan
- Medicines used to treat diabetes
- Medicines used to suppress the immune system such as ciclosporin, cyclophosphamide, tacrolimus and methotrexate
- Medicines to relieve pain and inflammation such as aspirin, ibuprofen and naproxen
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Medicines for epilepsy such as phenobarbitone, phenytoin and carbamazepine
- Medicines to reduce blood clotting ('thin' the blood) such as warfarin and heparin
- Some immunisations and vaccinations

- Medicines for myasthenia gravis (ongoing muscle weakness and chronic fatigue), glaucoma, Alzheimer's disease
- Medicines for psychiatric disorders and anxiety
- Medicines to help you breathe when you have lung diseases such as asthma, bronchitis and emphysema
- Medicines for nausea such as aprepitant and fosaprepitant
- Medicines for HIV (AIDS) such as indinavir, ritonavir and cobicistat
- Some medicines for blood pressure, stroke and other heart conditions such as digoxin and diltiazem
- Diuretic used to help kidneys get rid of salt and water from the body by increasing the amount of urine, such as frusemide, spironolactone and acetazolamide
- XOFIGO (radium 223 dichloride) for treating prostate cancer
- Grapefruit juice
- Medicines for breast cancer and hormone disorders

These medicines may be affected by YONSA MPRED, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

How to use YONSA MPRED

How much to take

YONSA MPRED contains two different medicines that need to be taken each day.

YONSA 125 mg tablets

The usual daily dose of YONSA is four 125 mg tablets taken as a single dose.

Methylprednisolone 4 mg tablets

Depending on your condition, the usual dose of the methylprednisolone 4 mg tablets in the YONSA MPRED pack is either one tablet once a day or one tablet twice a day.

Follow the instructions provided and use YONSA MPRED until your doctor tells you to stop.

When to take it

Take your medicine at about the same time each day.

YONSA tablets and methylprednisolone tablets can be taken with or without food.

How long to take it

Follow the instructions provided and use YONSA MPRED until your doctor tells you to stop.

If you forget to take it

YONSA MPRED should be used regularly each day.

If you miss your daily dose of YONSA or a dose of methylprednisolone, skip the dose that you missed and take the next dose when you are meant to.

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

If more than one daily dose is missed, talk to your doctor.

While you are using YONSA MPRED

Things you must do

Keep all of your doctor's appointments so that your progress can be checked. Your doctor will do some blood and other tests from time to time to check your progress and monitor for side effects. These include:

- Checking your blood pressure
- Checking that you are not getting fluid retention (bloating, swollen legs, feet, ankles, puffiness in the abdomen, face and hips, sudden unexplained increase in weight)
- Checking your heart is working normally
- Blood tests to check your potassium and sugar level and to check your liver is working normally.

Your doctor may do other tests as well.

Remind any doctor (including surgeons and anaesthetists), dentist or pharmacist you visit that you are using YONSA MPRED.

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

Call your doctor straight away if you:

- Are diabetic and notice a change in the results of the blood sugar tests.
- Notice signs of infection such as fever, swelling or inflammation.
- Notice signs that your blood potassium may be low such as muscle weakness, muscle twitching or heart palpitations.

Things you must not do

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

Do not stop using this medicine suddenly. Your doctor may reduce the dose of methylprednisolone gradually if you have been on long-term treatment.

Things to be careful of

Driving or using machines

Be careful before you drive or use any machines or tools until you know how YONSA MPRED affects you.

YONSA MPRED may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the chance of you experiencing stomach problems.

In case of overdose

If you take too much (overdose)

If you think that you have used too much YONSA MPRED, you may need urgent medical attention.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much YONSA MPRED.

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

Symptoms of an overdose may include an unusual heartbeat (too fast or slow, irregular), shortness of breath, fatigue or weakness, swelling in your legs, ankles and feet, persistent cough or wheezing.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using YONSA MPRED.

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

Less serious side effects

- Fatigue
- Cough
- Hot flushes
- Nausea
- Headache, dizziness or lightheadedness
- Muscle weakness, pain or loss of muscle mass
- Problems with your joints, including pain
- Thin fragile skin or bruising easily
- Itchy or peeling skin, rashes, acne, hives
- Slow wound healing
- Increased sweating
- Diarrhoea or constipation
- Indigestion
- Increased appetite, loss of appetite or weight loss
- Persistent hiccups

The above list includes the more common side effects of your medicine.

Serious side effects

- Signs of an allergic reaction such as skin rash, itching; difficulty breathing, wheezing or coughing; swelling of the face, lips or tongue
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers
- Heart palpitations (heart racing or pounding) or irregular heartbeat
- Pain or discomfort in your chest
- Blurred or distorted vision or loss of vision, eye infections
- Pain when urinating or blood in your urine
- Fluid retention (swelling or bloating)
- Swelling or discomfort in your joints, feet, ankles or legs
- Severe stomach pains
- Convulsions or fits
- Mood changes e.g. excitement, depression, suicidal thoughts, hallucinations, anxiety

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are uncommon.

Some side effects can only be found when your doctor does tests from time to time to check your progress, for example:

- Changes in liver function
- Increases in blood sugar (glucose) levels
- Increase in blood fat levels
- Changes in blood pressure
- Loss of bone density

- Reduced potassium levels in the blood
- Changes in the function of the adrenal glands, which make the body's own steroids

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

After using YONSA MPRED

Storage

Keep YONSA MPRED where the temperature stays below 25°C.

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

Follow the instructions in the carton on how to take care of your medicine properly. Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- In the bathroom or near a sink, or
- In the car or on window sills.

Keep it where young children cannot reach it.

Disposal

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Product description

What it looks like

YONSA MPRED is a combination pack which contains two different medicines supplied together in a cardboard carton.

YONSA tablets are white to off-white and oval shaped, marked with '125 FP'. YONSA tablets are supplied in a white plastic bottle containing 120 tablets.

Methylprednisolone 4 mg tablets are white to almost white, round, flat and scored tablets. Methylprednisolone 4 mg tablets are supplied in a white plastic bottle containing either 30 or 60 tablets.

Ingredients

Active ingredient(s):

- YONSA tablets contain 125 mg abiraterone acetate
- Methylprednisolone tablets contain 4 mg methylprednisolone

Inactive ingredients:

- YONSA tablets also contain: lactose monohydrate, sodium lauryl sulphate, butylated hydroxyanisole, butylated hydroxytoluene, microcrystalline cellulose, croscarmellose sodium and sodium stearyl fumarate.
- Methylprednisolone tablets also contain: lactose monohydrate, maize starch, gelatin, magnesium stearate and talc.

YONSA tablets and methylprednisolone tablets contain lactose.

Methylprednisolone tablets also contain sulfites.

Sponsor Details

YONSA MPRED is supplied in New Zealand by:

CARSL Consulting

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NEW ZEALAND

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Date of Preparation

This leaflet was prepared in December 2022.