

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using YONSA MPRED?

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

For more information, see Section [1. Why am I using YONSA MPRED?](#) in the full CMI.

2. What should I know before I use YONSA MPRED?

Do not use if you have ever had an allergic reaction to abiraterone acetate, methylprednisolone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use YONSA MPRED?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with YONSA MPRED and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use YONSA MPRED?

YONSA MPRED should be used regularly each day. The dosage recommended by the doctor will depend on your condition

More instructions can be found in Section [4. How do I use YONSA MPRED?](#) in the full CMI.

5. What should I know while using YONSA MPRED?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using YONSA MPRED.• Keep all of your doctor's appointments so that your condition can be monitored.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none">• YONSA MPRED may cause dizziness in some people. Be careful before you drive or use any machines or tools until you know how YONSA MPRED affects you
Drinking alcohol	<ul style="list-style-type: none">• Alcohol may increase the chance of you experiencing stomach problems
Looking after your medicine	<ul style="list-style-type: none">• Store your medicine in a cool dry place where the temperature stays below 25°C, away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Common side effects include diarrhoea, fluid in legs and feet, low blood potassium, urinary tract infection and high blood pressure. Other side effects include high fat levels in your blood, liver function test increases, indigestion, blood in urine, chest pain, heartbeat disorders, heart failure, rapid heart rate and muscle pains. Some side effects can only be found when your doctor does tests from time to time to check your progress.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

YONSA MPRED™

Active ingredients: *Abiraterone acetate and methylprednisolone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using YONSA MPRED. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using YONSA MPRED.**

Where to find information in this leaflet:

- [1. Why am I using YONSA MPRED?](#)
- [2. What should I know before I use YONSA MPRED?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use YONSA MPRED?](#)
- [5. What should I know while using YONSA MPRED?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using YONSA MPRED?

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 high 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.

2. What should I know before I use YONSA MPRED?

Warnings

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 have severe liver failure.
- If you are being treated with XOFIGO (radium 223 dichloride), a radiation therapy used for prostate cancer
- If you are pregnant or may potentially be pregnant
- if you have an infection or if you have recently been given a vaccine

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - problems with your liver or 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
 - emotional problems or mental disorders
 - infections
 - Cushing's disease (a hormone disorder)
 - seizures/epilepsy
 - myasthenia gravis (ongoing muscle weakness and chronic fatigue)
 - thin or weak bones
 - blood clots
 - systemic sclerosis
 - lactose, galactose or glucose intolerance
 - have muscle pain, weakness or dark urine — these may be signs of rhabdomyolysis.
- take any medicines for any other condition
- Talk to your doctor or pharmacist before taking Yonsa Mpred if you have an over-active thyroid gland (hyperthyroidism)

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using methylprednisolone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with methylprednisolone. You may need additional treatment to alleviate this condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

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

Some medicines and YONSA MPRED may interfere with each other. These include:

- medicines for bacterial infections (antibiotics) such as rifampicin, erythromycin, clarithromycin and isoniazid
- cough medicines such as dextromethorphan
- medicines used to treat diabetes, low blood sugar may occur to patients with pre-existing diabetes receiving pioglitazone or repaglinide.
- 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, 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

- diuretics 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.
- Other potassium depleting agents (such as amphotericin B, laxatives)
- XOFIGO (radium 223 dichloride) for treating prostate cancer
- grapefruit juice
- medicines for breast cancer and hormone disorders

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these can be used while you are taking YONSA MPRED.

4. How do I use YONSA MPRED?

How much to take / use

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 YONSA MPRED

- YONSA tablets and methylprednisolone tablets can be taken with or without food. The tablets should be swallowed whole with water. Do not crush or chew tablets.

If you forget to use YONSA MPRED

YONSA MPRED should be used regularly each day.

If you miss your daily dose of YONSA or a dose of methylprednisolone, skip the dose you missed and take your 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

If you use too much YONSA MPRED

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using YONSA MPRED?

Things you should 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
- Remind any doctor (including surgeons and anaesthetists), dentist or pharmacist you visit that you are using 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 should not do

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

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.

Looking after your medicine

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.

Getting rid of any unwanted medicine

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 • Painful lumps under the skin (panniculitis) • slow wound healing • increased sweating • diarrhoea or constipation • indigestion • increased appetite, loss of appetite or weight loss • persistent hiccups 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 • muscle breakdown (rhabdomyolysis), which may cause muscle pain, weakness or dark urine 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

YONA MPRED is only available with a doctor's prescription.

YONSA tablets and Methylprednisolone 4 mg tablets are not available separately.

What YONSA MPRED contains

YONSA tablets

Active ingredient (main ingredient)	abiraterone acetate
Other ingredients (inactive ingredients)	lactose monohydrate sodium lauryl sulphate butylated hydroxyanisole butylated hydroxytoluene microcrystalline cellulose croscarmellose sodium sodium stearyl fumarate.
Potential allergens	Lactose monohydrate

Methylprednisolone tablets

Active ingredient (main ingredient)	methylprednisolone
Other ingredients (inactive ingredients)	lactose monohydrate maize starch gelatin magnesium stearate talc
Potential allergens	lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What YONSA MPRED 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 60 tablets or 30 tablets.

YONSA MPRED is available in two pack sizes. Each carton of YONSA MPRED contains 120 YONSA tablets and either 60 or 30 methylprednisolone tablets.

YONSA MPRED registration number: Aust R 346890.

Not all pack sizes may be available.

Who distributes YONSA MPRED

Sun Pharma ANZ Pty Ltd

Macquarie Park Sydney NSW 2113

Telephone 1800 726229

Email: customerservice.aus@sunpharma.com

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